NIH AIDS Research Program Evaluation

BEHAVIORAL, SOCIAL SCIENCE, AND PREVENTION RESEARCH AREA REVIEW PANEL

Findings and Recommendations

Panel Members

Thomas J. Coates, Ph.D., *Chair*
Center for AIDS Prevention Studies (CAPS)
University of California, San Francisco (UCSF)
Judith Auerbach, Ph.D., *Executive Secretary*
Office of AIDS Research, NIH
John Bancroft, M.D.
Kinsey Institute
Floyd Bloom, M.D.
The Scripps Research Institute
Margaret Chesney, Ph.D.
CAPS/UCSF (liaison from Natural History, Epidemiology, and Prevention Panel)
Sherry Deren, Ph.D.
National Development and Research Institutes
Rafael Diaz, Ph.D.
CAPS/UCSF
Ferd Eggan
AIDS Program, City of Los Angeles
Loretta Sweet Jemmott, Ph.D., R.N., F.A.A.N.[1]
University of Pennsylvania
Jeffrey Kelly, Ph.D.
Center for AIDS Intervention Research, Medical College of Wisconsin
Judith Levy, Ph.D.
University of Illinois, Chicago
Michael Merson, M.D.
Yale University
Richard Price, M.D.
San Francisco General Hospital and UCSF
Michael Shriver
National Association of People With AIDS
Freya Sonenstein, Ph.D.
The Urban Institute
Ezra Susser, M.D., Dr.P.H.
Columbia University

OAR Staff Support
Paul Gaist, M.P.H., Senior Program Analyst
Diane Jones, Program Assistant
Sherri Cooper-Smith, Program Assistant

[1]Served until September 25, 1995

Table of Contents

Executive Summary

Fifteen years into the AIDS epidemic behavioral and social change remain essential and effective tools for preventing HIV transmission. Even if preventive vaccines, more promising drug therapies, or other biomedical preventive interventions are developed in the near future, they will have to be combined with behavioral and social strategies in order to be used effectively on a global level. In addition, because the number of AIDS cases worldwide remains high and continues to grow, social and behavioral strategies for managing its consequences will be necessary for a long time to come.

Priority Areas

Against this backdrop, the Panel on Behavioral, Social Science, and Prevention Research reviewed the NIH AIDS research program in relevant fields and developed recommendations in four areas, in order of priority:

- **Primary Prevention—Intervention Research**, which is of the highest priority and should be coordinated with efforts in biomedical prevention and vaccine research.

- **Primary Prevention—Basic Behavioral and Social Science Research**, which provides the essential underpinning of intervention research and deserves full and complete support at the NIH.

- **Consequences of HIV Infection**, which encompasses issues in HIV prevention among the HIV-infected as well as the psychological, social, psychiatric, and neurologic consequences of HIV disease.

- **Methods in Behavioral, Social Science, and Prevention Research**, which need to be further developed, expanded, and validated.

The Panel concurs strongly with the NIH AIDS Research Program Evaluation Working Group (EWG) recommendation to establish a Prevention Science Advisory Group, reporting directly to the Director of the Office of AIDS Research (OAR) and co-chaired by individuals with expertise in biomedical as well as social and behavioral science. The Panel also concurs with the report of the Panel on Natural History, Epidemiology, and Prevention Research on the need to establish a coherent and coordinated prevention research plan for the NIH, the Department of Health and Human Services (DHHS), and the Federal Government as a whole. Both of these strategies will help address the recommendations made in relation to the priority areas noted above.

Guiding Principles

The Panel derived five principles to guide research across priority areas in Behavioral, Social Science, and Prevention Research:

1. Behavioral, Social Science, and Prevention Research is underfunded at the NIH and, in order to be effective, requires coherence and coordination across the Institutes, Centers, and Divisions (ICDs).
2. HIV/AIDS research must respond to the evolving course of the epidemic and must focus on populations most vulnerable to the spread of HIV.
3. Research supported by HIV/AIDS funds must be relevant and contribute to finding solutions to the epidemic. A clearer definition of AIDS-related research should be developed.
4. NIH research should complement activities at the Centers for Disease Control and Prevention (CDC) and other Public Health Service (PHS) agencies and Federal departments.
5. International HIV/AIDS research in the behavioral and social sciences must continue to be supported by the NIH.

Primary Prevention—Intervention Research

The Panel found that the NIH has made significant progress over the past 15 years in developing effective interventions to prevent the spread of HIV in vulnerable populations. The National Institute of Mental Health (NIMH) primary prevention/intervention portfolio has produced interventions useful in preventing HIV in many populations at highest risk for the sexual transmission of HIV, including gay and bisexual men, adolescents, the homeless, and the mentally ill, as well as urban, disadvantaged, and predominantly ethnic minority populations. The National Institute on Drug Abuse (NIDA) has developed strategies for reducing HIV transmission among in-treatment and out-of-treatment injection drug users (IDUs), crack cocaine users, and their sex partners. The National Institute of Child Health and Human Development (NICHD) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) have funded small intervention research programs focused on youth and on the relationship between alcohol and high-risk behavior. But much remains to be done to ensure that successful interventions are employed effectively on a larger scale than they have been to date.

Recommendations for future work include:

- Continued reevaluation of populations vulnerable to HIV infection so that research can be focused specifically on their needs;

- Research focused on diverse levels of interventions including individual, small group, institution, community, society, and policy/law;

- Further refinement of research methods and outcome assessments, including consideration of when and where biological outcomes should be employed in behavioral interventions and when quasi-experimental versus experimental designs should be used;

- Encouragement to amplify work in cost-effectiveness and cost-utility analysis and biostatistical and mathematical modeling; and

- Continued emphasis on research that is useful to communities at risk for HIV infection and to agencies implementing programs in those communities.

The Panel was especially distressed that in FY 1994 (the focal year of this review) only 3.4 percent of the total NIH AIDS budget was devoted to primary prevention/intervention research in the behavioral and social sciences. When prevention research coded as Natural History, Epidemiology, and Prevention is added, the total comes only to 6.5 percent of all NIH AIDS research dollars. The Panel feels that this amount is woefully inadequate, given that preventive interventions are currently our best tool for limiting the spread of the HIV/AIDS epidemic.

Primary Prevention—Basic Behavioral and Social Science Research

Basic social and behavioral research is the essential underpinning of AIDS-related primary prevention and early intervention efforts. The Panel supports a strong program of basic research in this area. The Panel commends the ICDs for progress in developing a basic science base. In particular, the Panel notes that NIMH and NICHD have sponsored sexual behavioral surveys of the general population of the United States, as well as of selected populations, and that NIDA has conducted important quantitative and qualitative work to document HIV prevalence and incidence as well as risk behaviors among IDUs. NIMH, NIDA, and NIAAA also have sponsored theory-building workshops and programs among the major theorists of health behavior change and social network analysis.

The Panel's major recommendations for basic behavioral and social science research include:

- The need for a paradigm shift to develop models that are domain-specific with regard to sexuality and drug use and that recognize that risk behavior is embedded within personal, interpersonal, and situational contexts;

- Support for basic research on individual differences in human sexuality and drug use that takes into account cognitive, affective, cultural, and neurophysiological variables;

- Support for research on the direct effects of intoxicants on self-regulatory mechanisms; and

- Support for studies that investigate the maintenance of behavior change.

Consequences of HIV Infection

In an effort to prevent and modify the consequences of HIV infection to individuals, families, and societies, the Panel recommends supporting or expanding basic and intervention research in a number of areas, including:

- Preventing further spread of HIV by those already infected;

- Attenuating the individual distress and social stigma of either being HIV-infected or possessing the fear of being HIV-infected;

- Evaluating and managing the neurological and psychiatric disease complications of HIV infection;

- Modifying the impact of HIV infection on caregivers, loved ones, populations, and society;

- Facilitating patients' entry and retention in optimal programs of HIV care;

- Aiding patient adherence to HIV prophylactic and treatment regimens; and

- Aiding HIV clinical trials by enhancing recruitment, retention, and protocol integrity.

Methods in Behavioral, Social Science, and Prevention Research

Research methodologies in behavioral and social science should be further developed and expanded to move the field forward. The Panel makes recommendations relating to the following:

- Developing a consensus on the appropriate outcome measures for addressing specific questions;

- Developing new analytic tools for dealing with data with nonnormal properties; and

- Developing criteria for using observational, quasi-experimental, or experimental designs.

Funding Mechanisms

The Panel commends the ICDs for creative use of funding mechanisms to jump-start a field that had been constrained by the removal in the 1980s of financial support for the social and behavioral sciences in general, and by political restrictions on sexual behavior and drug abuse research in particular. For example, NIMH has used the Centers' grant mechanism to create centers of excellence in HIV prevention studies even while maintaining a majority of its funding in investigator-initiated grants. It has also used the Cooperative Agreement mechanism to conduct multisite clinical trials of important HIV preventive interventions, and it has created consortia of investigators to pursue specific research questions simultaneously in a variety of locations. NIMH has also been quite active in sponsoring workshops and symposia on important theoretical and methodological issues in the field.

Similarly, NIDA has used the Cooperative Agreement mechanism to develop important databases on the prevalence and incidence of HIV and high-risk behaviors among in-treatment and out-of-treatment IDUs, for focusing efforts on the development of novel treatments for drug addiction, and for developing innovative outreach strategies for bringing out-of-treatment IDUs into HIV preventive interventions.

Investigator-Initiated Grants. The Panel generally concurs with the EWG on the utility of investigator-initiated grants in the field of HIV/AIDS. However, to a much greater extent than ICD funding of other areas of HIV research, the ICDs represented in the Behavioral and

Social Science Research portfolio already have made use of investigator-initiated grants at the level desired by the EWG—approximately 50 percent of the total.

The Panel recommends that ICDs conducting behavioral, social science, and prevention research continue to use a range of funding mechanisms creatively in order to carry out priorities in this area.

Training

The training of new investigators, especially minority scientists, is a high priority. Among the ICDs, NIMH is to be commended for its training grant opportunities in HIV/AIDS research for Behavioral and Social Science Research. The Panel recommends increased funding for training in all relevant ICDs, especially that which is multidisciplinary and which will result in a measurable increase in the number of minority principal investigators (PIs) supported by the NIH.

Current Peer Review

The current peer review system at the NIH poses many problems that should be corrected. The Panel believes that it is imperative that the peer review groups be kept abreast of developments in NIH AIDS research priorities as articulated in the annual OAR-led NIH Plan for HIV-Related Research, and that an investigator's attention to these priorities be one basis for funding decisions. The Panel also believes that the current "triage" pilot program for grant review is a problem. Specifically, investigators need solid and noncontradictory feedback on their applications—which they are not receiving under this program—so that the applications can be improved upon in the future. The Panel, therefore, recommends discontinuing the "triage" approach.

Key Recommendations for Specific ICDs

NIDA should reverse the proportions of its treatment research portfolio and its harm reduction portfolio to give greater weight to the latter.
NIMH should give greater weight to intervention research than to basic research in the area of primary prevention.
The National Institute of Allergy and Infectious Diseases (NIAID) should not use its HIV Vaccine Efficacy Trials Network (HIVNET) program to conduct social and behavioral intervention studies unless or until the appropriate behavioral expertise can be integrated into the HIVNET governance and review processes.
NICHD should support more HIV preventive/intervention research focused on youth most vulnerable to HIV infection.
NIAAA should emphasize intervention over pre-intervention research and give greater resources to the former.
The National Institute on Aging (NIA) should resume its commitment to HIV/AIDS and aging research.

A Strong OAR

The Panel supports a strong OAR, especially because the research portfolio in behavioral, social science, and prevention research is spread across 10 ICDs and requires collaboration and coordination to remain coherent and to avoid unnecessary duplication. The OAR is needed to continually reassess research priorities, to ensure that priorities are being implemented, and to achieve greater coordination within behavioral and social science research and between this area and other relevant areas.

Introduction

The slow pace of developments in the search for a cure and a vaccine has prompted greater awareness that efforts aimed at preventing HIV and for managing the personal and social consequences of infection must be supported for many years to come. Because HIV is a disease whose transmission is driven by specific behaviors—primarily sexual and drug use—that occur in social contexts, efforts targeting behavioral and social change must continue to be an important tool of HIV prevention. Even if HIV preventive vaccines pass the rigors of clinical trials and become available for general use, they are unlikely to be 100 percent effective or reach 100 percent of the population, especially in the parts of the world that need them the most. The effective combinations of behavioral change and vaccination strategies will be essential for mounting and maintaining effective HIV prevention programs in the developed and developing countries. Moreover, because the number of AIDS cases remains high and continues to grow worldwide, social and behavioral strategies for managing the consequences of HIV infection will be necessary for a long time to come.

The Panel on Behavioral, Social Science, and Prevention Research was charged with developing scientific objectives and priorities for the next phase of HIV/AIDS research, examining the existing portfolio of NIH research, and making recommendations about the future of research at the NIH in this area. The Panel was constituted to represent diversity along a number of dimensions: academic discipline, community representation, ethnicity, geography, and serostatus. (A roster of Panel members may be found in Appendix B, and biosketches may be found in Appendix C.) The Panel met seven times, first on May 3, 1995, and finally on November 28, 1995. The Panel formulated its approach to the task, requested and reviewed key documents from the ICDs, met with AIDS program directors from the ICDs with research in this area (NIDA, NIMH, NIAID, NICHD, NIAAA, and the National Institute for Nursing Research [NINR]), and received additional documentation from NIA. The Panel also met with Dr. Wendy Baldwin, Deputy Director of Extramural Research at the NIH, to discuss issues and reforms in the peer review process. The sixth meeting, held on November 2, 1995, included a public session for comments from individuals and groups interested in providing input into the Panel's deliberations. The Panel also benefited from, and incorporated where appropriate, the findings and recommendations of prior evaluations of AIDS behavioral research conducted by the National Research Council, Institute of Medicine, and National Commission on AIDS (listed in the Reference section on page 58).

At its first meeting, the Panel divided its domain into four areas corresponding to the scientific priorities in the FY 1997 NIH Plan for HIV-Related Research:

1. Primary Prevention—Intervention Research
2. Primary Prevention—Basic Behavioral and Social Science Research
3. Preventing the Behavioral and Social Consequences of HIV Infection—Intervention and Basic Science Research
4. Methods in Behavioral, Social Science, and Prevention Research

Subpanels convened to review the NIH portfolio in each of these areas and to craft recommendations, which ultimately were endorsed by the entire Panel. Other, crosscutting

issues were discussed by the Panel as a whole and are presented in the section below titled "Special Issues in AIDS Research Funding." During this process, the Panel developed a set of overarching principles by which research needs for the future were identified and retrospective evaluation was conducted.

Principle 1: Behavioral, Social Science, and Prevention Research is important, critical, and underfunded at the NIH. In order to be effective, the portfolio in this area requires coherence and coordination.

Over the past 15 years, much has been learned and applied from behavioral and social science research on changing risky sexual and drug-using behaviors among a range of populations and groups. More recently, it has been recognized that, in addition to their application to understanding and changing risk behavior, social and behavioral science perspectives are critical to other, biomedical areas of AIDS research. In the realm of vaccines and therapeutics, for example, behavioral aspects of recruitment, retention, and adherence to clinical trials and access to and distribution of biomedical interventions once developed are important, but to date relatively neglected, concerns.

The Panel found that, in FY 1994, behavioral, social science, and prevention research received approximately 12.1 percent of NIH AIDS research funds. Of these funds, 3.4 percent was directed to Primary Prevention/Intervention Research, 6.2 percent to Basic Behavioral and Social Science Research, and 2.5 percent to Preventing the Consequences of HIV Infection. (There was no reliable way to determine the amount of money allocated to research on Methods.)

Recommendation

1. **Support for Behavioral, Social Science, and Prevention Research should be increased substantially to at least double its current level. This, in turn, should be allocated according to the scientific priorities identified in the annual update of the NIH Plan for HIV-Related Research.**

The Panel believes that a strong OAR is necessary to prevent fragmentation of the Behavioral, Social Science, and Prevention research portfolio, which is spread across 10 ICDs. It is difficult to maintain a coherent, scientifically focused program of research when the portfolio is so dispersed. Moreover, there appears to be a lack of correspondence in many cases between OAR and ICD priorities. Each ICD has a specific mission and conducts HIV research in line with that mission. Therefore, its scientific priorities might not always be consonant with those of OAR. The Panel believes that OAR coordination is essential to move beyond individual ICD orientations and to achieve a coherent and coordinated program of Behavioral, Social Science, and Prevention Research that reflects the scientific priorities established by this and other trans-NIH processes.

Recommendation

2. **The Panel recommends that OAR take a leadership role, using its Coordinating Committee mechanism, to ensure that the scientific priorities identified for AIDS-related behavioral and social science research at the NIH are responsive to the recommendations of this report, and that as newly emerging issues are identified, research is initiated to address them. The Coordinating Committee should include external (non-NIH) members and be used to stimulate trans-ICD and transdisciplinary activities. Examples of such activities include developing joint Request for Applications (RFAs), establishing lead agencies for specific priorities, and establishing coordination with other PHS agencies (e.g., CDC, Substance Abuse and Mental Health Services Administration [SAMHSA], Health Resources and Services Administration [HRSA]).**

Principle 2: HIV/AIDS Research Must Respond to the Evolving Course of the Epidemic

The Panel began its task by formulating the important scientific priorities in Behavioral, Social Science, and Prevention Research. It believes that a forward-looking document should not be driven by past trends, but rather by important scientific issues and opportunities at this point in the epidemic.

HIV/AIDS research should be responsive to changes in the epidemic. With respect to new infections in the United States, injection drug use currently accounts for approximately 50 percent, homosexual transmission accounts for approximately 25 percent, and heterosexual transmission accounts for approximately 20-25 percent. With respect to demographic factors, in the United States, Latinos and African-Americans are especially hard-hit by HIV, representing 18 percent and 38 percent of all AIDS cases, respectively; the proportion of cases among women has increased to 18 percent (from 8 percent in 1987); and approximately 50 percent of new HIV infections occur in individuals under the age of 25. Worldwide, 90 percent of new infections occur in developing countries.

Priorities in Behavioral, Social Science, and Prevention Research should be determined in response to major modes of transmission (injection drug use, homosexual, heterosexual, and perinatal) and by crosscutting demographic characteristics and geographic considerations related to the epidemic (e.g., youth—especially underserved youth—ethnic minority status, geographic areas of high HIV prevalence, relative poverty, and developing country). Priorities should be reevaluated continually in relation to changing modes of transmission. In addition, priorities may vary by geographic region of the country and should be related to ongoing trends in risk behaviors that may, in fact, precede changes in incidence of new infections. Therefore, monitoring such trends in behavior will be important.

Recommendation

3. **The NIH, with collaboration from CDC, should establish sentinel stations in key areas throughout the United States that have different levels of seroprevalence. This can have multiple benefits, such as providing the ability to (1) monitor changes in risk behaviors, (2) identify new risk groups, (3) evaluate both naturally occurring and planned intervention efforts in a timely manner, and (4) conduct pilot intervention**

research for later development of R01s. (An underutilized mechanism, the P-30 Center grant, may be suitable for providing funds for this type of multisite undertaking.)

Principle 3: Research supported by HIV/AIDS funds must be relevant and contribute to finding solutions to the epidemic. A coherent schema must be developed for use across the NIH in determining what research appropriately qualifies for support by AIDS research dollars.

The Panel grappled with developing its own definition and schema for AIDS-related research in the behavioral and social sciences. The results of this attempt may be found in Appendix A. The proposal found there is intended to spur a discussion across the NIH, led by OAR, that will ultimately culminate in operational schema that can be used by each ICD in each area of science.

The Panel believes that formalizing a definition of AIDS research is appropriate because separate funds have been designated by Congress for this area, and demand for accountability in the use of AIDS dollars is increasing. However, the Panel recognizes that some caution and judgment will always be needed in applying this or a similar system too rigidly. The overriding goal is to advance the AIDS effort as rapidly and smoothly as possible and to make full use of funds allocated for this purpose, not to make it more difficult to fund appropriate research.

Recommendation

4. **The OAR should develop guidelines, criteria, and a process for rating the AIDS-relevance of projects funded with NIH AIDS dollars. To implement this coding scheme, the principal investigator on a proposal should be required to prepare a brief rationale justifying the AIDS-relevance of the project if AIDS funds are expected to be used to support the project. The study section would be charged with determining whether the project met the criteria specified by the OAR.**

Four criteria were used by the Panel for evaluating the AIDS-relevance of behavior-based intervention research programs in the NIH portfolio: (1) the extent to which the research focuses on populations vulnerable to HIV, (2) its potential for developing the most appropriate and effective intervention approaches, (3) the extent to which the current base of scientific knowledge is utilized, and (4) usefulness of the research to communities at risk. The Panel used these criteria to evaluate current funding trends and to make recommendations about programs that should be emphasized and those that should be reconsidered.

Principle 4: NIH Research Should Complement Activities at the CDC and other PHS Agencies, as well as Activities of Other Federal Departments and Agencies.

The Panel found that among the PHS agencies, the NIH is uniquely qualified to develop and conduct a comprehensive program of research in Behavioral, Social Science, and Prevention Research related to HIV/AIDS. As discussed in this report, this comprehensive agenda includes primary prevention/intervention research related to drug abuse, alcoholism, and risky sexual

behavior. It also includes the basic science base for intervention research, as well as basic and applied research on the consequences of HIV infection. The NIH has the necessary scientific expertise and infrastructure to conduct this comprehensive program of research in collaboration with scientists around the country.

Nonetheless, HIV-related Behavioral, Social Science, and Prevention Research at the NIH should not be divorced from activities at other PHS agencies, especially the CDC, HRSA, and SAMHSA. The CDC has responsibility for primary prevention programs, HRSA administers the Ryan White Care program, and SAMHSA is responsible for substance abuse and mental health services programs. The basic distinction between the NIH and other PHS agency activities is that the NIH primarily supports basic and applied research, while the other agencies primarily support services related to prevention and early intervention.

A major problem occurs in the flow of information between these agencies. The NIH should be proactive in disseminating research findings to other agencies. NIH research agendas should be responsive to the concerns raised by these agencies and developed with input from providers on the front lines of HIV prevention and care.

Recommendation

5. The OAR should stimulate coordination among the NIH and other PHS agencies responsible for primary prevention and early intervention in HIV. This process should establish mechanisms for assessing, on a regular basis, the concerns of front-line HIV providers and integrating these concerns into the NIH research agenda.

Principle 5: International HIV/AIDS Research in the Behavioral and Social Sciences Should be Supported by the NIH.

A global approach to effective social and behavioral science-based strategies for HIV prevention and care is an urgent necessity. The World Health Organization estimates that 10,000 infections occur daily in the developing world. The AIDS pandemic affects virtually all nations. HIV threatens the stability of worldwide economic and political structures. A concentration only on domestic HIV prevention would ignore the realities of rapidly increasing world trade, travel, and migration, all of which serve to expand the epidemic.

Nevertheless, the Panel found very little support for international behavioral and social science studies in the current portfolio. International research is justified both because developing countries offer unique research opportunities that may shed light on innovative intervention approaches in the United States and because, as noted above, the vast majority (90 percent) of new infections are occurring in developing countries. Furthermore, many of the countries hit hardest by HIV are least able to deal with the epidemic. Additionally, studies of the impact of variation in policies most certainly will require cross-national comparisons. Finally, in certain situations, studies conducted in developing countries have greater analytic power, especially if disease outcomes are used as endpoints.

Recommendation

6. **The Panel recommends ongoing and increased NIH support for international efforts in Behavioral, Social Science, and Prevention Research through the spectrum of funding mechanisms used by the ICDs.**

I. Review of Behavioral, Social Science, and Prevention Research at the NIH by Scientific Priorities

A. Primary Prevention—Intervention Research

Primary prevention of HIV infection through interventions targeting the sexual and drug use behaviors that put people at risk should remain the top objective of the NIH's AIDS-related behavioral, social science, and prevention research agenda. Much has been learned over the past 15 years from successful behavior change interventions, and it is now time to further refine and apply such interventions on a broader scale in an attempt to have an even greater impact on reducing the transmission of HIV.

The Panel found that approximately $41 million, or 3.4 percent of the total NIH AIDS research budget in FY 1994, supported primary prevention/intervention research. When prevention research coded as Epidemiology, Natural History, and Prevention is added ($37.8 million, or 3.1 percent of the NIH total), the amount comes to $78.8 million or 6.5 percent of all NIH AIDS research dollars. The Panel feels this is not a sufficient commitment to HIV/AIDS preventive/intervention research, and Recommendation 1 (above) is intended to redress this.

Within the area of primary prevention/intervention research, the Panel determined four priorities of equal significance and reviewed NIH programs and made recommendations accordingly. These priorities are:

- Focus NIH intervention research on those populations most vulnerable to new HIV infections.
- Ensure that HIV preventive interventions reflect the most promising behavior change models and address different levels of social organization.
- Further refine and improve intervention evaluation methodologies.
- Ensure that research-based preventive interventions are useful to communities and to agencies that implement HIV prevention programs.

Focus intervention research at the NIH on those populations most vulnerable to new HIV infections and in urgent need of preventive interventions. Certain populations and social groups are becoming increasingly vulnerable to HIV/AIDS. In the United States, these populations include gay youth and young adults, especially those of color; disenfranchised and impoverished women; heterosexual men, especially those of color; disenfranchised adolescents (including inner-city homeless and runaway youth); out-of-treatment substance abusers and

their sex partners; and inner-city homeless adults and the severely mentally ill. The Panel believes that these most vulnerable populations should be adequately represented in the preventive intervention portfolios of the ICDs.

Review of NIH Programs

NIH Institutes and Centers have made significant progress over the past 15 years in broadening the range of population groups included in their intervention studies. Currently, NIDA, NIMH, NICHD, and NIAAA support projects with many of the most vulnerable groups: out-of-treatment drug users, minority women, adolescents, sexually transmitted disease (STD) clinic patients, and urban and rural gay men.

With respect to HIV risk related to drug abuse, NIDA has focused its major preventive intervention research initiatives (National AIDS Demonstration Research [NADR] and Cooperative Agreement) on out-of-treatment IDUs and their sex partners (and, more recently, crack smokers). From the beginning of the epidemic, this group has been perceived to be the most vulnerable among drug users. The emphasis on individuals engaging in high-risk drug use behavior should be maintained in NIDA-supported AIDS research, particularly in high-prevalence areas, for those individuals engaging in high levels of risk behavior, and for those who may be resistant to reducing risks. At the same time, given the dynamics for many subjects of being in and out of treatment, and the fact that community outreach efforts, in conjunction with traditional drug treatment efforts, may have synergistic effects on HIV-related outcomes, studies that permit broader recruitment efforts and examine combinations of intervention efforts should now be undertaken. Other relevant populations that require additional focus include homeless youth (many of whom are drug users), gay and bisexual drug users (especially IDUs), women (at risk either through their own drug use or through sexual activity with drug users), and drug users in the criminal justice system. NIDA's recently issued program announcement (PA) on HIV prevention among women is timely.

The NIMH primary prevention/intervention portfolio also has focused on, and produced useful information about, many populations at highest risk for the sexual transmission of HIV infection, including urban, disadvantaged, and predominantly ethnic minority populations—in particular, women, adolescents, and STD clinic patients. NIMH also supports projects with the urban homeless and the severely mentally ill. NICHD contains within its small portfolio a few studies focused on African-American and Latino adolescents and women living in poor, urban areas. These are all very important populations on which to focus HIV preventive intervention research, given demographic trends in the epidemic.

However, one of the most vulnerable groups remains underrepresented in all NIH ICD behavioral and social science portfolios: men who have sex with men (MSM), particularly those who are also young, those who are members of ethnic minority groups, and those who abuse drugs and alcohol. Given the high incidence of infections in young or ethnic minority MSM, increased prevention attention to these populations is needed. In addition, because male attitudes toward condom use or deferral of sex have considerable influence on risk reduction, and because male resistance to condom use has been well established as a deterrent to HIV

protective behavior change, an increased HIV prevention focus on heterosexual men at higher risk because of drug use or other recognized HIV vulnerability is also needed.

Recommendations

7. **NIDA should support research that recognizes the diversity among the drug-using population (and their social networks) vulnerable to HIV. Relevant groups include homeless youth (the majority of whom are drug users), gay and bisexual drug users (especially IDUs), women at risk either through their own drug use or through sexual activity with drug users, including women who trade sex for money or drugs, and IDUs and crack smokers in the criminal justice system.**

8. **NIMH should expand its prevention research to additional populations including young and ethnic minority MSM, heterosexual minority and poor men, and young people in situations that make them vulnerable to HIV risk behavior.**

Ensure that HIV preventive interventions reflect the most promising behavior change models and address different levels of social organization (individual, small group, institution, community, society, and policy). Intervention models should be tailored to the specific needs of various vulnerable populations. Much of the intervention research supported to date has been focused on behavior change among individuals and small groups, and has been informed by a limited set of theories and models that have led to designs that may not be appropriate or relevant for all populations. Now it is important to draw an adequate balance among interventions to change risk behavior, interventions to prevent the initiation of risk behavior, and interventions to maintain positive behavior over time and prevent relapse to unsafe behaviors; to move from small-scale intervention efficacy studies to larger-scale clinical or community trials; and to employ a more diverse array of intervention models that target different levels of analysis. It also is important to determine whether there are promising interventions in the international arena that may be pursued domestically, and to ensure that all interventions are adequately tailored to population factors. Cost-effectiveness studies of various intervention strategies should be undertaken by all relevant ICDs—individually and in collaboration with one another.

Review of NIH Programs

Across the NIH, HIV primary preventive interventions generally have been focused on the individual level, and little attention (with specific exceptions) has been given to broader interventions targeted to dyads, drug-using or sexual networks, community-wide efforts, or national policies. In addition, where successful interventions have been reported by NIH investigators, the specific components of the intervention that were most responsible for behavior change have not been identified.

Most intervention studies in the NIH portfolio appear designed to test single theories of behavior change, such as the test of a prevention/intervention based on social cognitive theory. While such approaches may be theoretically pure, changing HIV risk behavior in enduring fashion in the real world may require drawing upon multiple conceptual perspectives,

combining multiple levels of intervention, and providing sustained supports for behavior change. Evaluations of multiple element, model, and delivery mode interventions do not always lend themselves to a research paradigm requiring the test of a single theory. Efforts should be made to encourage greater innovation and multiple channel approaches.

Most of the HIV preventive intervention studies reported in the literature employ brief followup periods to ascertain efficacy (usually 1 year or less), even though HIV is a chronic and ongoing threat for which long-term maintenance of changed behavior is essential. Research is needed to identify strategies that can promote consistent and sustained risk-reduction behavior change. While high-intensity small-group interventions have been shown to be efficacious, these interventions are impractical for use in many public health settings. Research therefore is needed to determine the "dosage" effects of preventive interventions and the effectiveness of brief interventions. The Panel commends NIMH for recently issuing program announcements designed to encourage research on relapse prevention and brief interventions. NIDA is to be commended for its early efforts to support research on the use of networks for HIV interventions. (NIAAA also has supported network analysis.) There is a need, however, for other drug-use-related HIV intervention research that addresses the issues on multiple levels, i.e., from the individual to the societal level. Specific studies are needed to evaluate interventions to reduce the progression from noninjection drug use to injecting drugs; assess the impact of changing paraphernalia laws on risk reduction; evaluate the effectiveness of various potential risk-reduction agents (e.g., drug user groups, shooting gallery managers, family members); and further develop "harm reduction" as an intervention strategy.

Within the HIV primary prevention field in general, there is a need to move from small-scale efficacy studies toward larger scale, multiple-site field trials of prevention models that show initial evidence of efficacy. Larger scale field, clinical, or community trials can help to establish generalizability of results and determine effectiveness in field or "real world" settings. NIMH has supported research of this kind in its Multisite Trial (described below) and in some individual investigations. This is very desirable, and research should be directed to future multisite, field trial, or other expanded trials of promising intervention models. The use of biological endpoints in this and other prevention trials where appropriate is encouraged.

Recommendations

9. **The NIH should support more research that assesses the social, environmental, and cultural factors influencing changes in risk behaviors. Cross-national studies may be particularly useful for conducting research with units of analysis larger than the individual.**

10. **In addition to studies of the sociocultural influences on risk behaviors, the NIH should encourage research that permits the identification of specific elements of successful interventions that may be related to behavior change (e.g., outreach, counseling, skills training, peer influences, or other components).**

Further refine and improve intervention research outcome assessment methodologies. It is important to use behavior change followup assessments adequately, to identify useful

intervention outcome designs that have been underemployed and to test them, and to ensure that issues related to the unit of analysis be addressed in a reasonable fashion, recognizing the simultaneous need for scientific rigor and the demands of quickly developing interventions to limit the spread of the epidemic. Most important in outcome assessment is the need to recognize when and where different intervention outcome assessment methods should be used.

Review of NIH Programs

Most followup studies of interventions have ended after a 6-month to 12-month period. Longer term followup studies are needed to assess the impact of interventions on the maintenance of behavior change. These studies should incorporate a qualitative research component to understand factors related to behavior change. In this regard, research is needed to improve followup methodologies, including research on how to achieve high followup rates, measurement of behavior change, and use of qualitative methods to assess behavior change and improve accuracy of self-report.

Many of the outcomes presented from intervention research focus on overall risk reduction in the population studied, and this may obfuscate important individual differences in response to intervention. For example, subjects may demonstrate varied patterns of change, including increase in risk behaviors, maintenance of high levels of risk behaviors, and reductions in risk behaviors, subsequent to an intervention. Studies of those individuals who reduce risks, as well as specific focus on those who may increase risks or be resistant to change, may yield important results for targeting future intervention efforts.

HIV primary prevention/interventions are usually evaluated by means of self-reports of behavior change. In order to enhance confidence in the validity and reliability of results based on such self-reports, research is needed to identify suitable corroborative methods and corroborative indices of risk behavior change. Prevention studies that incorporate innovative confirmatory behavior change measures should be encouraged and made a high priority.

As mentioned above, most of the NIH-supported intervention research employs the individual as the unit of analysis for assessing change. As community-, institutional-, or societal-level interventions are undertaken, evidence of community, population, or other supra-individual indices of change will be needed.

Community-level HIV primary preventive interventions that follow traditional random-assignment clinical trial designs are extremely expensive given the number of units needed when communities are the unit of analysis. To address the need for interventions that focus on communities rather than on individuals, without incurring the cost of randomized trials, the NIH should encourage the use of quasi-experimental design alternatives. These permit community-level trials to be undertaken in field-demonstration studies that are more modest in scope than those that would be needed in true randomized trial designs. Indeed, the NIH should encourage studies that employ methodologies appropriate to the range of disciplines that come under the rubric of “prevention science,” including epidemiology, social and behavioral science, communication science, clinical medicine, biostatistics, health services research

economics, and laboratory science. No one methodology should be seen as having universal primacy within the prevention science arena.

Analyses of the outcomes of most HIV preventive interventions rest exclusively on behavior change outcomes. It will be useful to obtain and analyze data that shed light on the cost-effectiveness and cost-utility of behavior change interventions in order to delineate the expense of particular interventions in relation to their benefits, especially by assessing the number of potential infections averted. This information will also be helpful to public health policymakers and consumers of HIV preventive interventions.

Recommendations

11. **The NIH should encourage and support the use of quasi-experimental design alternatives (to the randomized controlled trial) that permit community-level trials to be undertaken in field-demonstration studies.**

12. **The NIH should encourage and support studies that assess the cost-effectiveness and cost-utility of behavior change interventions, including those that estimate or measure the number of potential HIV infections averted by an intervention.**

Ensure that research-based preventive interventions are useful to communities and to agencies that implement HIV prevention programs. Interventions designed mainly to test theories and to contribute to the development of intervention science *per se*, are often perceived to have limited utility to communities most affected by HIV/AIDS. It is vital in the context of the AIDS epidemic to ensure that research-based interventions are made useful in their public health applicability. Determining how best to change research to better ensure its use by communities, public health entities, and policy planners is a scientific question. Implicit in the issue of the translation of research to community practice is the question of how "street" knowledge acquired by service providers, for example, is integrated into the research designs of NIH grantees, as well as how research findings, where appropriate, are translated for use on the "streets."

Review of NIH Programs

NIH ICDs vary in their level of connectedness to communities and service providers. In addition to the usual routes of research dissemination, such as publication of scientific articles in peer-reviewed journals, in-house publications sent to select individuals and institutions, and fact sheets that are made available through telephone and (increasingly) electronic mail clearinghouses, a few ICDs have attempted to make direct linkages to community groups.

For example, NIMH, with the support of OAR discretionary funds, recently established a consortium of researchers, community representatives, and service providers to develop a model of effective dissemination of HIV preventive interventions. The NIMH Centers program also has emphasized dissemination and technology transfer and has established strong programs of community-based research and exchange. This approach recognizes the imperative to both protect the integrity of a research design and respect the needs and capacities of communities.

NIAID has a more formal mechanism for integrating its research activities with community planning and service delivery: the community advisory boards (CABs) affiliated with NIAID's clinical networks (e.g., ACTG and CPCRA) and HIVNET. The CABs are intended to provide community input into the scientific agenda and governance of the clinical units and are considered an important forum for the staff of the groups, community members, health care providers, and community advocates to exchange information and share ideas concerning clinical trials, study design, and other factors affecting accrual and adherence. **(See Recommendation 5 above.)**

B. Primary Prevention—Basic Behavioral and Social Science Research

Basic behavioral and social science research is the essential underpinning of primary prevention and early intervention efforts. The Panel identified six priorities for supporting a strong program of basic research and reviewed NIH programs and made recommendations accordingly. The priorities are:

- Conduct basic research within groups and populations that have been or are more likely to be affected by the AIDS epidemic, giving special attention to those vulnerable groups that to date have been underrepresented in NIH research programs.

- Shift the basic research paradigm toward the development of models that are domain-specific with respect to sexuality and drug use, focus on the breakdown of the intention-behavior relation, and recognize that risk behavior is embedded within a given sociocultural context.

- Understand the determinants of HIV risk behavior within the broader context of individual, dyadic, and group differences in human sexuality and drug use.

- Expand current research efforts on the impact of drug and alcohol use on the sexual transmission of HIV, including studies that examine how individual and group differences in patterns and types of consumption affect sexual behavior.

- Develop a clearer understanding of how HIV risk might change within individuals and dyads over time as a function of developmental and life course events.

- Understand individual differences in the ability to initiate and maintain behavior change relevant to HIV prevention, with particular emphasis on the modifiability of certain types of sexual behavior and potential individual differences in susceptibility to risk-reduction interventions.

Conduct basic research within groups and populations that have been or are more likely to be affected by the AIDS epidemic, giving special attention to those vulnerable groups that to date have been underrepresented in NIH research programs. Because HIV spreads most expeditiously among members of certain “core” high-risk groups and at an increasing but slower pace from members of these groups into the general population, the most effective and cost-efficient approach to reducing AIDS lies in focusing primarily on those high-risk,

high-transmission groups that are most vulnerable to infection. HIV prevention research, therefore, should target groups and populations according to sound epidemiological data on prevalence and incidence of HIV infection.

Review of NIH Programs

The NIH has supported a number of studies designed specifically to study vulnerable groups, such as young gay men, women of color, out-of-treatment drug users, and adolescents of color. IDUs and older adolescents are well represented in HIV prevention research at the NIH. The particular attention to runaway and street youth at NIMH is highly commendable, as is the attention to out-of-treatment IDUs at NIDA. However, in the FY 1994 portfolio there was only one research program at the NIH specifically designed to study issues of HIV prevention in gay men of color.

Consistent with current NIH policy, the majority of studies make a significant effort to include ethnic minorities in their samples, and many studies oversample in order to obtain substantial numbers of ethnic minorities in representative samples. It is not clear from the FY 1994 grant abstracts, however, whether and/or how variables, instruments, and study procedures are modified to obtain meaningful data from ethnic minority groups. While most theory-building studies include ethnic minorities, minority participants are typically used to assess the validity of hypothesized relations in nonwhite populations. Very little work is done to build theoretical models based on observational data from ethnic minority populations, where ethnic/cultural variables are prominent or central to the behavior model. Similar concerns exist for research on women (for example, female IDUs), with the relative paucity of theoretical models informed by issues of gender and culture.

Recommendations

13. **Basic research supported by NIMH, NICHD, and NIDA should be conducted within the following high-risk, understudied groups: gay men of color, young gay men, women who have sex with IDUs, bisexual men, and gay and bisexual drug users.**

14. **The following groups, currently with lower HIV prevalence, also merit special study because of their potential vulnerability: persons who are mentally ill, incarcerated persons, young adolescents (under 15 years of age), and later middle age and older adults. Research involving these groups should be supported by NIMH, NICHD, NIDA, and NIA, as appropriate.**

Shift the basic research paradigm toward the development of models that are domain-specific with respect to sexuality and drug use, that focus on the breakdown of the intention-behavior relation, and that recognize that risk behavior is embedded within a given sociocultural context. To a large extent, observational (and some intervention) research has been guided by a set of relatively well-known models of behavior change (e.g., the Health Belief Model, Theory of Reasoned Action, Stages of Change, and Self-efficacy Model). While extremely useful and productive for HIV prevention research, many of these models are seriously limited. They were originally formulated for domains other than sexuality and drug

use and emphasize and/or were designed to predict the personal formulation of individuals' behavioral intentions. They assume that the behavior in question is under individual volitional control, and, consequently, they tend to overlook the processes—personal, interpersonal, and situational—involved in the enactment of intentions in the face of multiple competing factors. With respect to sex in particular, these models fail to consider the specific effects that sexuality or sexual arousal may have on such processes. In addition, many of the theories focus on cognitive/perceptual factors and, for example, will give more weight to individuals' perceptions of control rather than to actual determinants of individual control over health-promoting behavior.

Models should be developed that focus on the difficulties that persons, dyads, and communities face in the enactment of personal intentions. Of special importance would be an attempt to understand risky behavior not in terms of "deficits" in individuals' knowledge, motivation, or skills, but rather as behavior that may have meaning and be quite understandable within a given sociocultural context. In this regard, more research is needed that focuses on units of analysis other than the individual (for example, studies that look at how whole communities adopt or resist HIV prevention measures), as recommended previously in this report and in other reviews (Institute of Medicine 1994, 1995).

Review of NIH Programs

A clear strength in current NIH-supported research is the inclusion of social context variables in studies of sexual and IDU risk taking. In particular, a substantial number of studies supported by NIDA are examining the role of specific social networks as regulators of sexual and drug activity. Several research projects funded by NIMH involve in-depth analyses of specific domains of variables that may affect sexual risk behavior (e.g., gay identity, ethnicity, family factors, crowd membership, gender issues, and developmental readiness). These studies are opening new avenues to understand and explain both barriers and facilitators of HIV risk behavior change in different populations. This kind of theory-scrutiny work has the potential to lead to the understanding of the limitations and domain-specificity of some popular models of behavior change.

On the other hand, there are too few qualitative/descriptive/ethnographic studies of the subjective difficulties individuals experience in their attempts to practice safer sex or of the situations/contexts that are subjectively experienced as difficult for practicing safer sex. The voices and experiences of those struggling to practice safer sex in difficult circumstances seem to be absent from HIV prevention theory construction and validation.

Recommendations

15. NIDA, NIMH, NICHD, and NIAAA should support theory-building studies that are specifically developed in the context of HIV prevention research, in contrast to studies that simply apply or adapt theories from other domains.

16. NIDA, NIMH, NIAAA, and NICHD should support qualitative/descriptive/ ethnographic studies of the subjective difficulties individuals experience in their

attempts to practice safer sex or safer drug-using behavior, and of situations/contexts that are subjectively experienced as difficult for enacting and maintaining safer behavior.

17. **All ICDs with a behavioral and social science portfolio should support basic research that involves units of analyses other than the individual.**

Understand the determinants of HIV risk behavior within the broader context of individual, dyadic, and group differences in human sexuality and drug use. High-risk sex and drug use behavior may occur because they serve purposes that compete with risk reduction (e.g., fostering intimacy, enhancing self-esteem, asserting dominance of masculinity, escaping a "reality" that may be painful, fitting in with peers). The use of sex and drugs in these various ways reflects sociocultural influences. Such tendencies, however, may interact with individual differences in personality characteristics and/or neurophysiological patterns of response to determine further the likelihood of high-risk behavior. Thus there are some individuals who are prone to take risks and other individuals who feel they have little control over their own fates. In addition, there is growing evidence of central inhibitory mechanisms controlling sexual response, which in some individuals are overactive, rendering them vulnerable to sexual dysfunction, and in other individuals underactive, depriving them of the biological safeguards which for most individuals adaptively counterbalance the effects of sexual arousal.

Review of NIH Programs

Noticeably lacking in the NIH research portfolio are clearly articulated hypotheses involving specific personality variables or the interaction between information processing and neurobiological mechanisms underlying sexual response as they impact sexual risk behavior.

Recommendation

18. **NICHD and NIMH, individually or collaboratively, should support basic research on those individual differences in human sexuality—cultural, cognitive, affective, and neurophysiological—that impact the sexual transmission of HIV. For example, attention should be paid to the relevance of the relationship (i.e., intimate/romantic, involving strong emotional bonds) on sexual risk behavior, and also to neurobiological mechanisms that might interfere with sexual self-regulation in the context of safer sex practices.**

Expand current research efforts on the impact of drug and alcohol use on the sexual transmission of HIV, including studies that examine how individual and group differences in patterns and types of consumption affect sexual behavior. Whereas there has been considerable attention paid to the relationships between both alcohol and drug use and risk taking, the specific interaction between substance use and sexual response has been largely ignored apart from anecdotal comments. For example, it seems quite possible that, in the presence of alcohol or drug intoxication, condoms will not be used because penile erections are already precarious.

Review of NIH Programs

Although many studies have looked at the relationship between patterns of individuals' substance use and/or abuse and individuals' reported sexual risk behavior, it is still not clear how sexual risk taking is directly impacted by the use of intoxicants. Within the area of HIV preventive behavior, there are virtually no studies of the effects of alcohol and/or drug consumption on the sexual response or on the self-regulation of sexual activity. Moreover, research is still equivocal regarding the increased likelihood of risky sexual behavior while under the influence of alcohol and/or drugs. Recent data from the CDC suggest that this area of research is particularly important for certain populations of gay men for whom the combination of drug use (including the use of methamphetamines) and risky sex heightens the possibility of HIV transmission.

The committee noted that there is substantial experimental literature on the effects of alcohol on sexual response in men and women. However, this literature predates the AIDS epidemic and apparently has never been properly linked to the study of HIV risk behavior. The Panel commends NIAAA for its current support of research on the relationship between alcohol use and sexual activity, and also commends NIDA for its recent initiation of investigations into basic and intervention research related to men who have sex with men and inject (or otherwise engage in the use of) drugs.

The underlying neurobiology of response to drugs, including the relevant "reward systems," has been and is being intensively studied. From the materials provided to the Panel by the ICDs, it appears that there are no comparable investigations of such mechanisms in relation to human sexual response or investigations on how drug-induced and sexually induced response systems interact. Yet these are researchable and potentially important issues for the development of effective HIV preventions.

Recommendations

19. **NIAAA, NIMH, and NIDA should support studies that examine in detail the use and abuse of alcohol/drugs within the context of sexual encounters and the direct effects of these intoxicants on sexual self-regulatory mechanisms.**

20. **NIDA and NIAAA should devote special attention to research on the impact of drug and alcohol use on the sexual transmission of HIV among gay men and on how initiation into alcohol and/or drug use might have an impact on sexual risk taking among adolescents.**

21. **NIDA should expand its support for studies on the exchange of drugs for sex and sex for drugs to include substances other than crack cocaine.**

Develop a clearer understanding of how HIV risk might change within individuals and dyads over time as a function of developmental and life course events, such as childbearing decisions, separation/divorce, and aging. Participation in behaviors leading to HIV transmission is correlated with a number of factors that reflect the passage of time and

maturation processes: biological age, stages of development, life course events, and stages of romantic and family relationships. Research is needed to better describe how HIV risk varies across these states. We also need a better understanding of how biological, psychological, and social processes combine to produce change in an individual or a dyad's HIV risk over time.

Review of NIH Programs

There has been a considerable amount of research devoted to adolescents' risk behavior. While these studies are commendable, more work is now needed to understand transitions into HIV risk behaviors such as substance use and sexual behavior (both homosexual and heterosexual). Barriers to this work include the absence of younger adolescents (i.e., those under 15) in study samples and the absence of longitudinal studies. The current Adolescent Health Study (Add-HEALTH), sponsored by NICHD with cofunding by numerous ICDs and the OAR, addresses some of these shortcomings, but additional qualitative and survey-based studies are needed to develop a better understanding of how young adolescents make the transition into or resist HIV-related risk behaviors.

At the other end of the age spectrum, adults over the age of 50 are not the focus of much AIDS research at NIH. Although this group is not believed to be one of the most vulnerable to HIV infection, its risk should not be ignored. Little is known about older persons' HIV risk behaviors, the experience of being HIV-seropositive in late adulthood, or the interactive effects of biological and social aging on AIDS-related attitudes and behaviors across the later life course. Certain biological changes that accompany the aging process are believed to influence sexual HIV transmission in older adults—decreased vaginal lubrication, the thinning of the vaginal wall, and reduced sexual arousability—that may depress condom use in older men. Given the life course issues that affect HIV transmission, NIA could play a vital role in furthering AIDS prevention through a proactive research plan that includes sponsoring or cosponsoring AIDS studies that include older persons. Indeed, a life-course perspective on HIV risk is a good area for collaboration among NICHD, NIMH, and NIA.

Recommendations

22. **NICHD and NIMH should support research on the sexual transitions of young adolescents including research on the initiation into homosexual and/or heterosexual activity and the related "coming out" or "experimenting" processes. In addition, studies are needed that investigate the biological and social precursors of these transitions, particularly when they are not voluntary.**

23. **NIDA and NICHD should support research on the progression of substance use over time. Recent findings suggest that first-time initiates and younger drug users are turning to forms of noninjection drug use in part to avoid HIV transmission. Studies are needed that investigate and map possible progressions into riskier forms of drug use in relation to HIV transmission.**

24. **NIA should collaborate with NIMH and NICHD to support more descriptive research about the HIV risk behavior of individuals who are in life stages and/or transitions that**

increase risk. These groups include pregnant unmarried women, recently divorced men and women, and individuals over the age of 50.

Understand individual differences in the ability to initiate and maintain behavior change relevant to HIV prevention, with particular emphasis on the modifiability of certain types of sexual behavior and potential individual differences in susceptibility to risk-reduction interventions. Currently, behavior change and maintenance of protective behavior over time are the only available strategies for preventing transmission of HIV. Even if a vaccine becomes available, behavioral factors related to its administration will remain important. Consequently, more resources should be devoted to understanding how behavior change occurs and how behavior is maintained over time.

In attempting to change any complex pattern of behavior by intervening, considerable variability in the extent to which individuals or groups respond to the interventions are to be expected. This "prognostic variability" should lead those intervening to select their method of intervention to suit the particular subject. Such directed interventions become possible after suitable investigations of the factors that distinguish between those who need and do not need the interventions to begin with, and between those who respond and do not respond to a particular intervention.

Review of NIH Programs

The Panel found no studies in the FY 1994 portfolios of the ICDs of "resilient" or "successful" individuals who, in spite of all odds, manage to maintain safer sex or drug use behavior over time. Similarly, the Panel found no studies of impulsive or "addictive" sexual behavior, that is, circumstances in which (or individuals for whom) volitional processes in sexual activity are easily broken down. There seem to be no systematic efforts at the NIH to understand individual or group differences that may explain treatment "failures,"
that is, characteristics of individuals and/or groups that may explain why they are not changed by or susceptible to current intervention efforts. Very few studies have specifically addressed the issue of maintenance and/or relapse in safer sex or safer drug use practices.

The first generation of basic behavioral research studies regarding risk behaviors primarily used cross-sectional designs to count the prevalence of behaviors and to investigate their correlates. Similarly, theoretical models in the field have tended to favor rational choice models that are better suited to explaining a single instance of behavior than patterns of behavior over time. The next generation of studies should be prospective or longitudinal so that behavior can be observed over time and causal models can be tested.

Recommendations

25. NIMH, NICHD, and NIDA should support research on "resilient" individuals who, in the face of difficult circumstances, are successful in adopting and maintaining safe sex and/or drug-using behavior.

26. NIMH and NICHD should support research on the relationship between "sexual addiction" and HIV risk taking.

27. Intervention studies funded by NIH should analyze systematically the reasons, variables, and/or characteristics that may explain individuals' susceptibility (or resistance) to HIV interventions.

28. NIMH, NICHD, and NIDA should support longitudinal studies of individuals' and/or groups' ability to maintain safe behavior over time and of those factors that may inhibit or promote relapse to unsafe practices.

C. Consequences of HIV Infection

Preventing and modifying the consequences of HIV infection as they relate to behavior broadly defined involves a number of issues, such as preventing further spread of infection by those already infected; attenuating the individual distress and social stigma of both infection and the fear of infection; evaluating and managing the neurological and psychiatric diseases complicating infection; modifying the impact of infection on caregivers, loved ones, and societies of those infected; facilitating patients' entry and retention in optimal programs of HIV care; aiding patient adherence to prophylactic and treatment regimens; and similarly aiding clinical trials with respect to recruitment, retention, and protocol integrity. Behavioral and social science research makes important contributions in each of these areas. The Panel identified six priorities for research on the consequences of HIV infection and reviewed NIH programs accordingly. These priorities are:

- Develop a comprehensive research program directed at preventing transmission by HIV-infected persons that includes studies to assess the determinants and prevalence of risk behavior and studies to develop, implement, and evaluate interventions designed to reduce risk behavior among infected subgroups.

- Develop strategies to prevent the adverse psychological and social consequences of HIV infection and to assist HIV-affected populations in coping with HIV infection and maintaining quality of life.

- Prevent and treat the neurological disease sequelae of HIV infection.

- Initiate a research program designed to facilitate HIV-infected persons' early access to testing and entrance into programs of health monitoring and appropriate intervention, including prophylaxis for opportunistic infections (OIs) and treatment to reduce disease progression.

- Define the scope of the problem of adherence, recruitment, and retention in HIV clinical trials and care. Identify the factors that influence these important behaviors, and design and test interventions to increase adherence, recruitment, and retention in HIV clinical trials and care.

- Examine the consequences of HIV/AIDS on the health care delivery system, including drug treatment systems. Conversely, examine the impact of changes in the health care delivery system on HIV/AIDS care and transmission.

Develop a comprehensive research program directed at preventing transmission by HIV-infected persons that includes studies to assess the determinants and prevalence of risk behavior and studies to develop, implement, and evaluate interventions designed to reduce risk behavior among infected subgroups. Decreasing risk behavior in HIV-seropositive persons has a significant potential for reducing HIV transmission because HIV-infected persons form the reservoir from which new infections occur. Given that risk of transmission may be high during primary HIV infection, early identification and testing of HIV-infected persons is important. There has been limited research on risk behaviors among HIV-infected persons. Most of this research has been conducted with samples of gay men and IDUs. The results indicate that while approximately two-thirds of these groups follow safe behaviors, the remaining one-third engage in behaviors that are associated with HIV transmission. Rates of risk behavior tend to be higher among younger gay men, but little is known about rates among other HIV-infected persons, including women, adolescents, persons infected at birth who survive to become sexually active, those who are homeless, mentally ill, or incarcerated, and patients with neurological disease.

Research is needed to develop targeted interventions for reducing risk in these special populations. For example, the likelihood of vertical transmission of HIV can be significantly reduced by antiretroviral treatment of HIV-infected pregnant women. The factors that influence decisions by pregnant women who undergo antiretroviral treatment, as well as the factors that influence more general reproductive decision making by HIV-seropositive women and men, must be identified so that effective programs designed to minimize HIV transmission can be designed.

Review of NIH Programs

There has been very limited descriptive or intervention research at the NIH on risk behavior among HIV-infected persons. Over the last decade, cohort and other observational studies documented risk behavior by HIV-infected persons with little attention to correlates of risk. Exceptions to this lack of research were a few descriptive studies supported by NIMH and NIDA of HIV risk behaviors among HIV-infected gay men and IDUs, studies underway in the NIMH Centers on risk reduction among couples with discordant serostatus, and a NIDA- and NIMH-supported research project to reduce both substance use and sexual risk behaviors among HIV-seropositive youths in three HIV epicenters. There is no evidence that risk behavior is assessed in subjects enrolled in clinical trials, and there have been no nested studies of interventions to reduce risk behaviors in these subject pools.

Recommendation

29. NIMH and NIDA should support (in some cases in collaboration with other ICDs) research to prevent transmission by HIV-infected persons, including studies to determine the prevalence and determinants of risk behavior among HIV-infected

persons and studies to develop and test interventions to reduce behaviors that place others at risk.

Develop strategies to prevent the adverse psychological and social consequences of HIV infection and to assist HIV-affected populations in coping with HIV infection and maintaining quality of life. People living with HIV disease are confronted with a number of challenges to psychological well-being that include progressive debilitating illness, stigmatization, medical regimens that have unclear benefits or serious side effects, and a highly variable and unpredictable clinical course. Increased access to HIV testing has and will continue to allow many people to learn that they are infected with HIV earlier in the course of their disease. While this is important for the effective clinical management of HIV, it also means that many people will live with the knowledge of their condition for many years, even before they are symptomatic. These persons need effective, early interventions to reinforce their care-seeking behavior, reduce the risk of their transmitting infection to others, and maintain optimal quality of life. As the illness progresses to its symptomatic stage, HIV-infected persons need to cope with the day-to-day challenges the disease poses to their physical and psychological well-being.

Research is needed on the prevalence and impact of adverse psychological reactions, including depression, which is characteristic of HIV-infected persons and often interferes with functioning and adherence to care. This research needs to examine these reactions and their impact in all the affected populations, including the homeless, IDUs, and the mentally ill. More needs to be known about the timing, duration, and severity of episodes of depression and other affective or psychological reactions, about their effects on social and psychological functioning and on health, and on the extent to which interventions can ameliorate these effects and consequences. Furthermore, there is a need to understand how these reactions contribute to risk behavior and viral transmission, involvement in and adherence to care, and effectiveness of sustained social and support systems. It is important to implement and measure the effect of interventions to manage depression and maintain positive states of well-being in various affected populations. Innovative interventions and treatment delivery strategies also should be developed for men, women, and children with late-stage HIV disease who may be homebound or physically debilitated.

Formal health care providers and informal caregivers, including family members, are critical links in the delivery of health care to HIV-infected persons across the spectrum of the disease, including the terminal stage. It has been suggested that this care has significantly cut costs without compromising treatment. Research is needed to establish the extent to which HIV care is delivered through informal channels, determine the quality of the care provided, and investigate the advantages and disadvantages of relying on informal caregivers. This research should examine the impact on the health and quality of life of those under care and the effect of this care on the social and psychological functioning of health care providers and informal caregivers. Clinical trials of alternative strategies for delivery of care including formal and informal caregivers are needed to determine optimal approaches to management of HIV disease in various populations.

The HIV epidemic has significant social consequences that can be observed at diverse levels and institutions of social organization, including the individual, family, school, workplace, jail and prisons, and geographic or cultural community. HIV-infected persons experience this impact in terms of social stigmatization (Public Media Center 1995). Research is needed to describe the effects of social stigmatization on HIV-infected persons' vulnerability to psychological distress, maintenance of social roles such as student or employee, ability to access and adhere to care, willingness to disclose HIV serostatus (e.g., to partners, families, health care providers, etc.), and practice of health behaviors that prevent the further transmission of HIV.

Limited research in selected populations indicates that stigma also creates barriers to support and care. In cases where there has been vertical transmission, some parents hold the dual roles of HIV-infected patient and caregiver for infected children. The psychological burden experienced by these and other parents is not well characterized. Little is known about the psychological effects of HIV disease and its stigma on children, including those who are and are not infected and those who later survive as orphans. What is known indicates that the strain on caregivers and siblings is significant and lasting. More research is needed to determine the effects of HIV disease on family and other close relationships, the factors associated with these effects, and the extent to which they can be ameliorated by social or behavioral interventions.

Review of NIH Programs

NIMH has sponsored considerable research on the effects of HIV disease on patients, caregivers, family, and children. This research has involved HIV-infected men, women, and drug users and has addressed a range of issues including disclosure of HIV serostatus and social stigma. NIMH also supports longitudinal studies of depression over the progression of HIV, trials of cognitive-behavioral interventions to improve coping and health behaviors among HIV-infected men and women, and studies of pharmacological treatments for psychological consequences of HIV disease. Prior to the AIDS epidemic, NIMH sponsored research on coping with other chronic diseases, including cancer. The investigators supported by this earlier funding are now applying their models to samples of persons with HIV/AIDS.

NINR extramural and intramural AIDS research focuses on studies of the quality of life among AIDS patients and interventions to assist HIV-infected persons in managing their HIV infection. The National Center for Research Resources (NCRR), through its General Clinical Research Centers (GCRCs), has supported a limited program of research on the adverse consequences of HIV, but it is not clear from the materials provided to the Panel what this research entails.

NIAID has supported little work in this area, aside from reports on the psychological impact of HIV disease in the Multicenter AIDS Cohort Study (MACS). However, the Panel believes that NIAID cohort studies, clinical trials, and the GCRCs offer opportunities for research addressing this priority. Nested studies of interventions to assist HIV-infected persons or caregivers in preventing or managing the adverse consequences of HIV infection have not been conducted in these groups but could be carried out utilizing appropriate behavioral science expertise in study design and implementation. Beyond the advantages in avoiding costly recruitment, these cohorts are well characterized and have regular assessments of biological outcomes. NIAID

should collaborate with NIMH, NINR, and NIDA to address important questions regarding the consequences of HIV infection in existing cohorts.

Recommendations

30. NIMH, NIDA, NICHD, NIA, and NINR (as relevant) should increase intervention research directed toward improving coping and quality of life among HIV-infected persons from all populations, across the full time-course of HIV illness.

31. NIMH and NIDA should expand research describing the impact of HIV disease on formal and informal caregivers, as well as on family members, and they should increase intervention research designed to address the needs of these groups.

32. NIMH and NIDA should initiate research on the impact of stigmatization on HIV-infected persons, including the influence of stigmatization on coping with HIV disease, decisions regarding treatment, and quality of life.

Prevent and treat the neurological disease sequelae of HIV infection. HIV infection leads to certain neurological diseases that appear to be caused by the AIDS retrovirus itself, rather than by secondary opportunistic infection. These include conditions that affect both the central nervous system (CNS) and peripheral nervous system (PNS). Most important among the CNS diseases is the AIDS dementia complex (ADC), which is also referred to as the HIV-associated cognitive/motor complex. The most common and important PNS disease is the painful distal motor polyneuropathy (DSPN). The precise underlying development of these disorders remains enigmatic. Because the morbidity of these conditions is often high and current treatments are either only partially effective or not effective at all, new and more effective prevention and treatments are needed. Therefore, understanding the interaction of HIV with the CNS and PNS is important to comprehending the biology of the virus and the mechanisms by which the virus can cause host cell dysfunction and important disease of the brain and nerves. (See also the discussion of neuro-AIDS in the Etiology and Pathogenesis Area Review Panel Report.)

Better understanding is needed of the ecology of HIV as it relates to the brain at all stages of infection—from primary viremia through clinical latency to late secondary high-titered viremia—along with efforts to prevent or attenuate exposure of CNS and PNS tissue. This includes understanding of the evolution and role of neurotropic and neuropathic genetic variants of the infecting virus. Reducing the high morbidity and mortality associated with these common disorders will require studies to define the consequences of infection and of host reactions to infection at the organ, cellular, and molecular levels through these stages of systemic infection and research to augment defenses and reduce immunopathology.

At the organ level, it is important to understand the selective involvement of certain brain structures and the mechanisms responsible for subcortical dementia and myelopathy of the AIDS dementia complex and its associated constellation of cognitive, motor, and behavioral alterations, which can vary in severity and clinical impact, from mild difficulty in concentration to devastating loss of mental and motor capacity. At the cellular level, research is needed to understand the vulnerability of particular cell types to HIV infection, the character of infection

that depends on both cell type and cell state, and the cell-cell interactions that result in pathology. The defenses within the nervous system that suppress or eliminate infection at different stages of systemic infection also are critical.

At the molecular level, research is needed to understand the importance of viral subtypes, the viral receptors, and the transcriptional and other intracellular mechanisms underlying abortive and latent infection, selected gene expression and replication in neural cells, and cells trafficking into the nervous system. Finally, research is needed to understand the molecular basis of reception, mediation, and consequences of intercellular signaling and neurotoxicity involved in causing brain and nerve dysfunction. Such research could lead to the development and testing of interventions modifying these processes. Modification of unique factors associated with HIV infection of children also need to be defined. These questions require research at multiple levels, from human studies (including clinical trials of prevention and therapy aimed at multiple mechanisms), to animal and cell culture models, all exploiting contemporary virological, neurobiological, and molecular methodologies.

Review of NIH Programs

NIMH and NINDS have been most active in supporting work in this area, and NICHD and NIAID also have contributed to this effort. NIMH and NINDS have been major supporters of laboratory studies of animal and cell culture models, of human studies aimed at defining the clinical, pathological, and virological features of the AIDS dementia complex and peripheral neuropathies, and of the related epidemiology and natural history in adults. Both Institutes support broad-based and important studies in these areas, particularly through their extramural programs using R01, Center grant, and Program Project mechanisms to advance the field. Additionally, some research has been conducted in intramural programs, including NIMH studies of quinolinic acid, a mediator of neurotoxicity that increases in the brains of patients with AIDS dementia, and studies examining behavioral changes in macaque monkeys infected with a retrovirus closely related to HIV, simian immunodeficiency virus (SIV). NIAID also has supported studies that contribute to defining natural history and therapy for these disorders through the Multicenter AIDS Cohort Study (MACS), the AIDS Clinical Trials Group (ACTG), and the CPCRA. NICHD similarly has supported critical studies on antiretroviral treatment of HIV-related brain disease in children. The best of these studies have defined the field and have included a broad and high-quality portfolio. Additional support has been provided by NIMH and NINDS for workshops and conferences to disseminate information and stimulate further work in these areas.

In the early years of AIDS funding, NIMH designated a number of studies as “AIDS-related” that, in retrospect, had uncertain mainstream relevance to AIDS and its more immediate neurobiological, psychiatric, and neurological problems. This included intramural and extramural projects, such as a broad range of studies of psychoneuroimmunology and research on other viral infections of the nervous system. Early in the epidemic it was not always clear what pathways would provide insight into neuro-AIDS and what cofactors might contribute to the timing of immunosuppression, so the decision to fund these studies may have seemed reasonable at the time. However, as the field has matured, NIMH has shifted its funding to research that by all accounts both reflects higher quality science and is more clearly related to

AIDS. The Panel commends NIMH for moving in this direction and urges it to continue doing so in both its intramural and extramural programs.

Because NIMH and NINDS have shared in the support of both laboratory and clinical studies of neuro-AIDS, there has been some overlap in their focus and redundancy in review procedures and administration. While this "competition" has not been entirely deleterious, as it has drawn on different expertise, encouraged diversity, and expanded the pool of investigators engaged in this important area, these programs should now be more closely coordinated for better effect. Because the subject matter falls within the traditional missions of both Institutes, with some variations in emphasis and expertise, both should continue to be involved in funding research in the area, but they should do so in a more coordinated fashion. NIMH and NINDS appear to be moving in this direction with the recent joint program announcement and funding of studies of altered blood-brain barrier and HIV. In the same way, review of grant applications in this area should involve common study sections organized through DRG (as now applies to other AIDS funding). NIAID and NICHD should also join this coordinated effort when there are similar overlapping scientific and programmatic issues and when it is appropriate.

Sharing and cooperation among ICDs should ensure that the necessary resources are available and the range of expertise working on these critical issues is maximized. Similar collaborations would benefit clinical trials related to neuro-AIDS, which also have been somewhat problematic, although perhaps more from having been neglected by the various ICDs than from being the subject of excessive competition. Such studies are important in addressing the high morbidity and mortality associated with neurological impairment. The most economical and sensible approach is to foster and coordinate inter-Institutional collaboration among NINDS, NIMH, NIAID, NICHD, and industry that has intermittently waxed and waned over the last several years. This collaboration should be more clearly directed, perhaps by the OAR, to pool resources and maximize the utility of this costly but much needed research.

Recommendations

33. **Conduct coordinated and collaborative research on the pathobiology of nervous system HIV infection and nervous system injury underlying the AIDS dementia complex, peripheral neuropathies, and other CNS and PNS complications of HIV and AIDS. These studies should be multidisciplinary efforts that focus on the cellular and molecular basis of viral latency, gene expression and replication in neural tissue, and the regional, cellular, neurochemical, and molecular basis of neural dysfunction. Research strategies should involve direct studies of human infection, animal models (including a spectrum of lentivirus models), and cell culture studies. NINDS, NIMH, NIDA, NIAID, and NICHD should work together to ensure that these studies benefit from broad expertise, state-of-the-art science, and the efficient utilization of resources.**

34. **Expand research on the treatment of the neurological and psychiatric sequelae of HIV infection. The scope of this research should range from cell culture and animal models to human clinical trials. These efforts should also involve cooperation and coordination among NINDS, NIMH, NIAID, NICHD, and other ICDs as appropriate.**

Initiate a research program designed to facilitate HIV-infected persons' early access to testing and entrance into a program of health monitoring and appropriate intervention, including prophylaxis for opportunistic infections and treatment to reduce disease progression. Testing positive for HIV infection is a pivotal event in a person's life. In most cases, this event is marked by brief counseling and a recommendation to seek medical care. The limited data indicate that many, if not most, HIV-infected persons do not follow the recommendations they receive and do not enter care at this time. Research focusing on persons hospitalized for HIV-related illnesses revealed that approximately one-quarter had not seem a physician prior to hospitalization. Another 40 percent of HIV-infected persons fail to get medical care until they experience major symptoms of HIV disease. The evidence that early therapeutic intervention with antiretrovirals may slow disease progression suggests that the observed delays in seeking care may have adverse health consequences.

Improving the link between testing positive for HIV and entering medical care is important in order to optimally manage HIV disease, including timely prophylaxis of co-infections. Research on opportunistic infections suggests that co-infections, such as *Mycobacterium tuberculosis* and *cytomegalovirus,* result in increased HIV replication and should be targeted for prophylaxis. Similarly, given that STDs increase the likelihood of HIV transmission and the rate of disease progression, the prevention and timely treatment of STDs is important in the care of HIV-infected persons.

HIV-seropositive persons encounter numerous economic, cultural, and psychosocial barriers when considering care. These can include limited access to health care facilities, community beliefs that there are not effective treatments, and loss of privacy. Health care barriers also are created by health care professionals who are not aware of new options for treatment and prophylaxis. Longitudinal studies are needed that examine the environmental, cultural, and behavioral factors associated with sustained health monitoring during asymptomatic phases of infection and during progression to the symptomatic phase.

Review of NIH Programs

There has been little research activity relevant to this priority at the NIH, with the exception of NIMH, which is funding research on the control of tuberculosis in HIV/AIDS patients.

Recommendations

35. **Initiate research to investigate the determinants and barriers to timely HIV testing and entrance into care by HIV-infected persons from all vulnerable populations.**

36. **Develop and test intervention strategies to increase the early identification, timely entrance into care, and effective management of disease in HIV-infected persons from all vulnerable populations.**

This research should be carried out collaboratively by NIMH, NIDA, NICHD, and NIAID, as appropriate to the populations addressed.

Define the scope of the problem of adherence, recruitment, and retention in HIV clinical trials and care. Identify the factors that influence these important behaviors, and design and test interventions to increase adherence, recruitment, and retention in HIV clinical trials and care. The effectiveness of clinical trials can be threatened by significant problems in recruitment, adherence, and retention. Estimates of adherence to protocols by study participants in earlier large clinical trials of antiretrovirals and in community-based research programs indicate that approximately one-third of subjects discontinue study medications; other participants report not taking the appropriate dose of the study medications and/or taking medications prohibited by the protocol. The extent to which similar problems exist for HIV-seropositive persons in care is not known. If these essential behavioral aspects of HIV treatment are not understood, the resources and efforts that are devoted to drug development and clinical trials will be undermined and important opportunities will be missed in the development of critically needed effective treatments.

Research is needed to accurately define the scope of the problems of adherence, recruitment, and retention in HIV clinical trials and to identify the factors that influence HIV-seropositive persons to enter, adhere to, and remain in clinical trials. This research should be extended beyond trials to the full range of populations of HIV-seropositive persons who need care, including populations that are difficult to reach such as the homeless and mentally ill. Among the factors that should be addressed are economic and environmental barriers to adherence such as the lack of transportation, child care, the cost of drugs and physician visits, cultural barriers such as mistrust of Government research and misinformation about treatment effects, psychosocial barriers including distress, neurologic complications of HIV, or substance use, and health care barriers including poor interactions between HIV-seropositive persons and health care professionals. The long-term nature of HIV disease requires that research examine treatment adherence and related issues over time, including factors associated with failure to maintain adherence, such as substance use.

The development and testing of strategies drawn from social and behavioral science to increase recruitment, adherence, and retention in clinical trials is needed immediately to maintain the integrity of the clinical trials. Similar research is required to improve the care of HIV-seropositive persons. The urgent need to improve adherence in clinical trial research and in care calls for a partnership among biomedical, social, and behavioral scientists.

New developments in assessment of HIV disease status and in therapeutics offer important opportunities for innovative research in this area. Such developments as the availability to measure viral burden could serve as a form of feedback for assessing adherence to treatment regimens and could supply valuable information to the provider regarding effectiveness of care.

Review of NIH Programs

There has been limited research at the NIH in the area of recruitment, adherence, and retention. NIMH has funded a study that involves both descriptive research and the development of a behavioral intervention to increase adherence and retention in HIV/AIDS clinical trials. The only other research specific to this priority is a study of adherence in HIV/AIDS clinical trials supported by NIDA and NIAID.

Recommendations

37. **NIMH, NIAID, and, where appropriate, NIDA should cooperate to support research to determine the social, psychological, environmental, and medical factors associated with recruitment, adherence, and retention in clinical trials and care for persons with HIV/AIDS.**

38. **NIMH, NIAID, and, where appropriate, NIDA should cooperate to support research to develop and test intervention strategies to increase recruitment, adherence, and retention in HIV/AIDS clinical trials and care by HIV-infected persons from all vulnerable populations.**

Examine the consequences of HIV/AIDS on the health care delivery system, including drug treatment systems. Conversely, examine the impact of changes in the health care delivery system on HIV/AIDS care and transmission. The structural and economic impact of HIV/AIDS on the health care delivery system is an important area of research, particularly as the epidemic moves into new demographic groups and evolves as a chronic disease. At the same time, the impact of changing health care delivery systems on the care of people with HIV/AIDS is equally important to investigate. Current and impending changes to the structure and administration of Government programs such as Medicaid and Medicare and the move toward managed care in both public and private health care plans undoubtedly will have an effect on access and quality of care for people with HIV/AIDS. Social scientists have the capacity to study these issues, in particular as "naturally occurring" phenomena. The NIH, in cooperation with AHCPR, SAMHSA, HRSA, and other relevant Federal agencies, should support this line of research. Within the NIH, relevant ICDs include NIDA (especially for drug abuse treatment systems) and NIMH (especially for mental health service systems).

D. Methods in Behavioral, Social Science, and Prevention Research

Research methodologies represent an essential component of the infrastructure of HIV-related behavioral and social research. Unfortunately, this component has not been adequately developed. The limits of current methodology seriously constrain our ability to draw representative samples of groups at high risk, measure and understand their behaviors, analyze the relationship of their behaviors to HIV transmission, and determine whether their behaviors can be changed. These constraints are especially frustrating because the methodological issues are not insoluble. Much could be achieved by refinement and extension of existing methods, as major new breakthroughs generally are not required.

No Institute or research program can be held accountable for this circumstance. In fact, methodological issues have not been overlooked by the ICDs. Each has made significant efforts to foster research on methods. For instance, NIMH and NIDA have sponsored meetings of experts to address specific areas in need of development (e.g., models of behavior change, technology transfer, cost-effectiveness analysis, and social network analysis). The results of these conferences have had a major impact in advancing behavioral research, and, partly due to these efforts, methodologies in some areas are developing rapidly.

Nonetheless, the overall coordination and central direction of methodological research have been weak. Methodological work is often duplicated by investigators confronting similar problems. The development of a new method tends to be left incomplete after its application to a specific study is over. Experts are drawn together in a most productive way, but only for one or two occasions rather than on an ongoing basis.

To meet the challenge of the epidemic, we need to not only generate new ideas but also focus efforts to resolve "rate-limiting" problems, effectively disseminate methods, and achieve rapid consensus on new methods. This need for focused methodological development is especially salient in HIV prevention. Conventional randomized controlled trials are suited primarily to the testing of individual-level interventions. But individual-level interventions are not, in general, directly applicable to societal-level prevention, which is required to arrest the epidemic.

Develop consensus on the appropriate outcome measures for various research objectives. HIV prevention research supported by NIMH, NIDA, NICHD, and NIAAA historically has relied on self-report data to measure behaviors. While self-reports are used widely in epidemiological research to establish risk factors for disease transmission, their validity is questioned when used as outcome measures in intervention trials. Three areas require attention: (1) research and consensus to determine the best combination of strategies to increase validity of self-reports; (2) research to determine the limitations on disease outcomes for prevention trials; and (3) research and consensus to determine when self-reported behaviors, HIV incidence, or other disease outcomes are the appropriate measures to use in outcome research.

Conduct statistical research to develop more powerful methods of analyzing data with nonnormal distribution properties. Distributions of sexual and drug-using behaviors tend to be extremely nonnormal, with many zeros at one end and "telling tails" at the other end. These distributions limit the utility of standard techniques for describing and comparing sexual behaviors of populations and for modeling epidemic transmission.

The behavioral and social science research community (internal and external to the NIH) should develop consensus on the kinds of research questions best answered by observational, quasi-experimental, or experimental studies, including randomized designs and community-level intervention trials. The Panel does not agree with recent reviews (e.g., by Oakley et al. 1995) indicating that the only valuable evidence to prove the efficacy of interventions is the randomized controlled trial. The methods for testing individual-level interventions in the conventional design of the randomized clinical trial are widely known and well developed. The randomized clinical trial tends to be held up as the "gold standard" for community-level interventions, even though such designs may be unfeasible, impractical, expensive, not useful for testing specific kinds of interventions, and may lack external validity. Effective HIV prevention, however, requires testing of interventions directed toward communities (or settings or societies) as well as individuals. These interventions need to include components at multiple levels and may include assessing policy and legislative changes as well as more traditional approaches to behavior change.

Foster the development of alternatives to the randomized controlled trial at the individual level so that they may be more fully elaborated and disseminated for wider use by

researchers. When scientific, ethical, or practical considerations preclude a randomized controlled trial, rigorous testing is still required. The basic statistical validity of some alternative allocation methods, such as the Assured Allocation design, has been established.

In addition, there is a need for systematic and generally agreed upon criteria for the use of data from various types of study designs to determine the presence or absence of a causal relationship. The relevance of convergent validity from results of different designs should be explicitly acknowledged. Acceptable approaches to synthesizing results from heterogeneous studies need to be established and disseminated to researchers.

Recommendations

39. Because methodological issues transcend specific ICDs, the OAR should establish committees of experts and support them on an ongoing basis to develop standards regarding the use of various design options and guidelines for the appropriate use of various outcome measures (e.g., self-reported behavior, incident STDs, or HIV).

40. The ICDs should develop programs, using the RFA or contract process, to stimulate methodological research on the issues identified in this report or through the ongoing process of scientific priority setting under the direction of the OAR.

II. Special Issues in AIDS Research Funding

A. Mechanisms

The Panel reviewed tables produced from FY 1994 budget figures to assess the use of different funding mechanisms for AIDS-related Behavioral, Social Science, and Prevention Research (in this section referred to as "BSSR").

1. Research Project Grants (RPGs): BSSR received about 13 percent of the total dollars spent on investigator-initiated projects across the five scientific areas of AIDS research. This amount was nearly evenly distributed between noncompeting (25 percent) and competing (21 percent) grants. As is true in other AIDS research areas, the NIH expended less than 1 percent of its AIDS money for BSSR-related Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) grants.

2. Research Centers: BSSR centers received the highest proportion (19 percent) of funds for centers among the five scientific areas. (Vaccine research was second, with 12 percent.) This primarily reflects the strong investment in BSSR centers by NIMH and NIDA, although in the latter Institute this may be due to a coding anomaly, as NIDA coded its Treatment Research Centers as supporting mainly Behavioral Research.

3. Research Training: Training received less than .02 percent of the total BSSR dollars, although this was a higher proportion than all other scientific areas. BSSR training clearly is not currently a top priority within the NIH AIDS budget. (See the separate discussion of training below.)

4. Intramural Research: BSSR represents a minor component of the NIH intramural research program in AIDS. Where intramural research is coded as "Behavioral Research," there is some question about its appropriateness (e.g., drug treatment research), as discussed elsewhere in this report.

In summary, it is important to note that the ICDs differ in the manner by which they code the contents of their portfolios according to the priorities of the NIH Plan for HIV-Related Research. These differences make it difficult and sometimes misleading to compare funding—both dollars and mechanisms—within and across AIDS areas and across ICDs. The Panel believes that better standardization of coding schemes is necessary.

Funding for Behavioral, Social Science, and Prevention Research appears to be fairly evenly divided between competing and noncompeting awards. This balance suggests that, overall, about half of this funding is directed toward new projects.

SBIR/STTR grants for AIDS research account for a very small percentage of the behavioral research budget. These awards encourage private sector, small business firms to invest in and develop AIDS-related products with high utility. Given their capacity to meet critical needs, these grants should be better publicized and encouraged for preventive interventions.

Research training with specific emphasis on BSSR is not promoted by NIH ICDs in any systematic or recurring manner that is discernible. Training programs and grants specifically targeted to BSSR are needed to draw new investigators into this area of AIDS research. (See the separate discussion of training below.)

NIMH AIDS Research Centers

Currently, NIMH supports five research Centers. Three of these Centers have a behavioral and social science emphasis: the HIV Center for Clinical and Behavioral Studies at Columbia University and the New York State Psychiatric Institute; the Center for AIDS Prevention Studies (CAPS) at the University of California, San Francisco (UCSF); and the Center for AIDS Intervention Research (CAIR) at the Medical College of Wisconsin. Two of the Centers have a neurobehavioral focus: the Center on AIDS Dementia: Molecular and Cellular Mechanisms at the Scripps Foundation in La Jolla, California; and the HIV Neurobiology Research Center at the University of California, San Diego (UCSD).

Because a number of people associated with these centers served on the Behavioral, Social Science, and Prevention Research Area Review Panel, a critical review of the centers program could not be undertaken without introducing significant bias. Moreover, those Centers recently were reviewed and reported on by the Institute of Medicine Committee on Substance Abuse and Mental Health Issues in AIDS Research (IOM, 1994). Therefore, what follows is primarily descriptive.

All of the NIMH Centers, except CAIR, are funded under the P50 mechanism and average around $3.5 million in FY 1994 funds. CAIR is funded under the P30 mechanism, which is capped at $750,000. The total amount of AIDS dollars dedicated to all of these Center grants in

FY 1994 was $16,418,870. This does not include separate R01 grants awarded to investigators affiliated with each site.

The intent of the NIMH Centers program is to support multidisciplinary teams of researchers with a thematic approach to HIV prevention. For example, the New York HIV Center has focused on heterosexual transmission and on hard-to-reach populations such as the homeless mentally ill, while CAPS at UCSF has focused on homosexual transmission, the intersection of substance abuse and risky sexual behavior, and heterosexual transmission in developing countries. The Center at UCSD focuses on basic and clinical research on the neuropsychiatric implications of HIV, and the Center at Scripps focuses on using animal models to elucidate the basic cellular and molecular mechanisms of HIV as it relates to the brain and central nervous system functioning. Each Center has spawned a number of individual R01s that further pursue its thematic orientation. Both the New York HIV Center and CAPS also support comprehensive training programs in AIDS behavioral research and have programs dedicated to linking researchers and their findings with community organizations and service providers in their region.

The Panel notes that, during the course of its activities, NIDA issued a new solicitation of proposals for comprehensive substance abuse research centers. Although the focus of these Centers need not be AIDS, HIV/AIDS is one area of substance abuse research that may be funded. Additionally, NIDA staff suggested that an AIDS-specific center announcement may be forthcoming.

B. Training

The NIH has a wide variety of mechanisms to fund research training, ranging from undergraduate research opportunities to scientist development awards. The multiple and diverse mechanisms include grants to individuals at different stages of career development, grants to fund specific training programs, and grants for the development of institutional infrastructure that would strengthen research training and/or access to research careers within the given institution.

A review of NIH AIDS-related funding for research training in FY 1994 reveals that a total of 206 awards totalling $19.6 million were made to individuals and/or institutions. Of those 206 training awards, 36 (or 17 percent) were identified by the NIH as involving the training of behavioral scientists. However, the Panel considered fewer than half of these training awards to be actually HIV/AIDS-related, although they were listed as having received AIDS funding. Specifically, in the NIH AIDS research training portfolio for FY 1994, the Panel could find only 17 awards that were clearly identified as both AIDS-specific and behavioral science. An additional 17 awards were clearly identified for training in behavioral research but were not AIDS-specific, and 2 awards were AIDS-specific but not clearly related to behavioral science. The bottom line is that only 17 (or 8 percent) of the 206 training awards listed as AIDS-related were actually for AIDS-specific behavioral science training.

The 17 training awards that were clearly both behavioral science and AIDS-specific were not well distributed across ICDs nor across funding mechanisms. Of these 17 awards, 7 were

supported by NIMH, 5 by NINR, 3 by NIDA, 1 by NICHD, and 1 by NIAAA. Six of the 17 were awarded for training programs, and 11 were awarded as individual fellowships at different institutions. All of the 6 training programs were funded by NIMH.

There is no indication in the materials reviewed that there exists at the NIH an organized and coordinated plan for behavioral science training in HIV/AIDS-related research. The Panel was not able to find in the materials identified as "training" for FY 1994 any career development awards ("K" awards) made to behavioral scientists for HIV/AIDS-related research. Furthermore, the Panel did not find a systematic approach to evaluate the outcome of training research awards and/or programs. For example, it is not clear whether funding training programs is more efficient and cost-effective than funding individual fellowships or research programs for the goal of increasing the number of new, qualified, and successful investigators in the NIH pool.

From this brief review, the Panel concluded that: the number and percentage of training opportunities for behavioral scientists that are specifically related to HIV/AIDS research should be increased from their current levels; NIAAA, NIDA, and NICHD should explore the possibility of funding training programs beyond individual fellowships, possibly in the context of existing HIV/AIDS research Centers; and NIMH should be commended for its leadership in funding HIV/AIDS research training programs. However, NIMH needs to clarify, specify, and justify the use of AIDS-related funds within research training programs that are not specifically AIDS-related.

Recommendations

41. Given the crucial importance of training for the research enterprise, the OAR should appoint a separate coordinating committee to review and make recommendations on NIH AIDS-related activities listed under "Training and Infrastructure" in the NIH Plan for HIV-Related Research.

42. The OAR should develop a coordinated plan for HIV/AIDS-specific behavioral science research training that takes advantage of a wider range of NIH training mechanisms (such as the K awards, supplements, and predoctoral research opportunities). The plan should include strategies for the systematic outcome evaluation of training awards.

Training of Ethnic Minority Investigators

Recently, the NIH reported that less than 3 percent of extramural projects funded between 1982 and 1991 were headed by African-American, Latino, or Native American investigators. This situation is troublesome on two accounts. First, the U.S. HIV epidemic is rapidly and disproportionally spreading in ethnic minority communities, and the expertise of minority scientists is crucial to prevention efforts. Second, the underrepresentation of minority scientists in the NIH pool coexists with a substantial number of programs designed to involve minority persons in research careers, so it appears that the programs are not working.

Part of the problem is that, beyond minority supplements to existing grants, the majority of NIH minority programs are targeted to the undergraduate and/or graduate predoctoral level. Because both supplements and predoctoral activities are typically carried out in the context of a more senior scientist's research program, it is unlikely that current NIH initiatives are helping promote minority independent investigators, as would be evidenced by an increase in minority principal investigators.

In the FY 1994 NIH portfolio for AIDS-related research training, the Panel was able to find only four initiatives that were explicitly identified as training of minority persons: (1) NIAID's minority predoctoral fellowship program at the University of Pennsylvania, $14,761; (2) NIMH's graduate fellowship program for ethnic minorities through the American Sociological Association, $56,915; (3) NIMH's minority training program in HIV research at the University of Michigan, $101,400; and (4) NIMH's undergraduate research training program at the University of Puerto Rico, $24,565. Three out of the four programs involve either undergraduate or predoctoral research. (The level of targeted research training for the fourth program is not clear, but it is likely to be also at the predoctoral level.)

Although listed under AIDS-related funding, only one of the traineeships targeted to minorities is explicitly related to HIV/AIDS. The Panel was encouraged to see that three out of four programs are sponsored by NIMH and, therefore, most likely involve training in behavioral sciences.

The total FY 1994 expenditure of funds for minority-targeted AIDS-related research training was $197,641. This represents about 1 percent of the total $1.9 million in funds spent by the NIH that year for AIDS-related research training.

Recommendation

43. The NIH should increase funding and programs for AIDS-related research training explicitly tailored and targeted to ethnic minority individuals, primarily at the postdoctoral level. These programs should involve collaborative mentoring activities in research projects defined by the minority scientists, rather than simply providing supplements to existing grants. Programs should include intense and long-term mentoring and support in the NIH grant application process, and they should be evaluated in relation to a measurable increase in the number of minority NIH-funded principal investigators at the NIH.

There are some limitations to our analysis of AIDS training initiatives, which the Panel would like to point out. While NIDA listed several awards for training in substance abuse treatment research, the Panel did not include them among the 17 because of lack of information regarding AIDS-relatedness and/or the involvement of behavioral science. Also, because of time limitations, we were unable to review the international research training programs listed under the activities of the Fogarty International Center.

C. Peer Review

Grant Review Problems

The Panel found a difference of interpretation between OAR and ICD priorities and what might be awarded fundable scores through peer review. While the peer review mechanism has served the NIH well, its seeming divorce from program priorities results in award decisions that may have little relevance to these priorities. The Panel believes it is imperative that NIH study sections be kept aware of scientific priorities in AIDS research as identified by the OAR through its planning and evaluation processes, which utilize the expertise of ICD program staff and the extramural community.

The Panel also concluded that there are problems with the current practice of "triage" piloted in the recently revised NIH grant review process. The goals of the NIH review process, in addition to identifying and funding meritorious applications, should include encouraging new investigators and providing feedback to all investigators regarding the review committee's recommendations for improvement of the proposal. The triage process, which provides only two reviewers' independent comments, without benefit of the combined wisdom that emerges from a committee's discussion, actually serves to discourage new investigators. Two independent reviews may have differing or even contradictory opinions. These may be confusing to the potential grantee, and they have been found to be inadequate in providing direction for resubmissions. Besides discouraging investigators, this practice can have a particularly negative impact on new investigators. Previously, the results of a study group's discussion usually provided helpful feedback, which focused on the critical issues that emerged from a group discussion. The Panel recommends that this aspect of the review process be reinstituted.

The Panel raised a number of other issues related to peer review but did not have sufficient time to discuss them thoroughly or to develop specific recommendations. Nevertheless, these issues deserve mention for future consideration, especially given the current discussion of how best to integrate the former ADAMHA Institutes (NIAAA, NIDA, and NIMH) into the NIH DRG system. These issues include the need to ensure that members of study sections include the range of expertise necessary to review all grants; the need for study sections to include primarily senior investigators, which can be accomplished only by loosening the overly strict conflict-of-interest rules that recently have been applied to reviews; the need to use percentile rather than absolute scores in making funding decisions, to reduce the bias related to committees' having different scoring "norms"; and the related need to address the problems created by "special reviews," where a new committee will be formed with different norms than the existing committee, thereby potentially biasing the scoring. The Panel believes that wherever possible, a grant should be reviewed by the appropriate regular study section, and conflicts of interest should be addressed through recusals of individuals with a perceived or real conflict with a particular proposal.

Recommendations

44. Priorities developed in this evaluation process should be used to guide the development of new RFAs by the ICDs.

45. **Study section composition should be informed by scientific priorities identified through this and other OAR processes. Study sections should be briefed regularly by OAR and ICD program staff on the scientific priorities identified through OAR processes.**

46. **Study sections should review grants for the degree to which they meet the scientific priorities established through this and other OAR processes.**

47. **In the next planning cycle, the Behavioral and Social Science Coordinating Committee should define not only priorities but also criteria for determining whether or not grants meet these priorities.**

48. **The NIH should eliminate the "triage" mechanism implemented in the recently revised grant review process.**

D. Other Issues

Difficulties in Coding Projects

In addition to the general problem of coding research projects as "AIDS-related" addressed earlier in this report, the Panel felt there was a similar problem with how projects are coded by scientific area (e.g., behavioral research, epidemiology research). Specifically, the Panel was distressed to find that coding of projects into areas of science and into objectives within these areas of the NIH Plan for HIV-Related Research was not determined by any consistent decision rules. Evidently, each ICD handles coding for budgeting, planning, and reporting purposes differently. In some cases, program staff assign codes to a project; in others, budget staff do so. Moreover, as the NIH Plan codes change from one year to the next, as a result of the annual OAR Coordinating Committee activity, projects are recoded to fit the new scheme, and it becomes impossible to track research programs over time. This becomes a real problem for ICDs, the OAR, and any external bodies wishing to track, review, or evaluate the NIH AIDS program. It is a problem that both the OAR and the ICDs must address.

Recommendation

49. **The Panel strongly recommends that the OAR, in cooperation with the ICDs and through the coordinating committee process, develop guidelines for coding AIDS research by scientific areas, and that these guidelines be used across future fiscal years to ensure that it will be possible to trust analyses of funding by areas of science and objectives, and to ensure that multiyear analyses will be possible.**

Missed Research Opportunities

Many excellent and interesting evaluations of HIV preventive interventions have occurred with "natural experiments," that is, with changes in legislation, policy, or social conditions that could presumably affect HIV transmission. Evaluation of these natural experiments is essential in developing and disseminating new tools for HIV prevention.

The Panel also notes that there are existing datasets developed from projects that may not yet have been fully utilized (e.g., from the NIDA National AIDS Demonstration Research projects). These datasets might provide rich resources for secondary analysis that would be useful to the funding ICDs and the broader community of interest. However, there may not be sufficient money in the ICD budgets for conducting such analyses.

Recommendations

50. Expedited funding should be made available to projects seeking to evaluate naturally occurring social or legislative changes.

51. The OAR should target funds to ICDs for secondary analysis of existing datasets.

III. Review of Select ICD Programs in Behavioral, Social Science, and Prevention Research

A. National Institute on Drug Abuse (NIDA)

The importance of drug use as one of the major forces currently driving the epidemic, for all populations, cannot be overemphasized. Therefore, it is critical that NIDA continue to take a lead role in research on this epidemic, particularly regarding the development and assessment of interventions for drug users. Currently, NIDA has the largest budget for AIDS-related behavioral and social science research among all NIH ICDs.

NIDA's entire portfolio for AIDS research in 1994 was approximately $138 million (34 percent of total NIDA funding and 11 percent of NIH AIDS funding). NIDA divides its extramural AIDS-related research programs into seven areas, four of which are related to behavioral intervention research and total $85 million. These four areas are: (1) community outreach to drug abusers and related individuals, $23.7 million or 28 percent; (2) research on needle exchange and needle hygiene, $2.4 million or 3 percent; (3) improving pharmacotherapies for drug abuse treatment, $23.3 million or 27 percent; and (4) improving nonpharmacological therapies, $35.4 million or 42 percent).

Pharmacotherapies and nonpharmacological therapies may be considered treatment research strategies, and community outreach and research on needle exchange and hygiene may be considered harm reduction research strategies. (By harm reduction, the Panel means strategies that seek to minimize morbidity, mortality, and discrimination among those people who already engage in drug use. The use of this term does not imply support for the legalization of currently illicit drugs.) Treatment research strategies received $58.7 million (69 percent) of the FY 1994 NIDA BSSR AIDS dollars, while harm reduction research received $26.1 million (31 percent). The Panel would like to see a different distribution between these two areas, with the greater emphasis on harm reduction approaches.

Recommendation

52. NIDA should reverse the proportions of its treatment research portfolio and its harm reduction portfolio to give greater weight to the latter.

NIDA Extramural Drug Treatment Research

In the early stages of the epidemic, NIDA responded to recommendations in two PHS plans (1986 and 1988) that emphasized the importance of drug abuse treatment in the prevention of HIV transmission among IDUs and their sex partners and offspring. As a result, NIDA expanded its treatment research programs targeting IDUs. Any treatment research study funded in response to a 1987 Program Announcement titled "Treatment of Intravenous Drug Abusers to Reduce the Spread of AIDS" was considered appropriate for AIDS research support.

Also, in the late 1980s, NIDA developed a program intended to improve pharmacotherapies for the treatment of addictions. Those therapies targeted to opiate addiction were supported by AIDS research money and continue to be so. From these early initiatives, NIDA's HIV/AIDS and drug treatment research program has evolved into two major components: developing pharmacotherapies for drug dependency and improving nonpharmacological therapies to reduce HIV risk behaviors.

The effort to develop pharmacotherapies for drug dependency, also known as the Medications Development Program, focuses on three areas: enhancement of the efficacy of drug addiction medications approved by the FDA, determination of the effectiveness of potential drug addiction medications that are currently marketed for a different indication, and determination of the effectiveness of potential treatment medications for cocaine and heroin addiction that are not currently marketed. These initiatives, supported extramurally through RPGs, contracts, and Centers, received approximately $23.3 million in FY 1994 AIDS funds.

Initiatives in nonpharmacological therapies to reduce HIV risk behaviors are categorized into two program areas. The first, begun in 1989, was the Research Demonstration Program to Reduce the Spread of AIDS by Improving Treatment for Drug Abuse. Eight Treatment Research Units were supported to conduct multiproject clinical research at major institutions. Also supported were 12 individual projects, 11 of which studied the effectiveness of both pharmacological and behavioral therapies in reducing drug dependence in controlled clinical trials. This program, however, was modified with the elimination of the R18 Research Demonstration Program grant mechanism.

The second area is the Behavioral Therapies Development Program (BTDP), a current initiative to systematically identify, develop, and test behavioral therapies for the treatment of drug abuse and dependence and, ultimately, to disseminate the most efficacious to clinicians. Behavioral therapies include counseling strategies, psychotherapies, rehabilitative techniques, and skills training approaches. The focus of this program is to reduce or eliminate the use of illicit drugs, and data are being collected on the impact of behavioral therapies on AIDS risk behaviors to document this effect.

Recently, NIDA expanded and focused its BTDP to encourage research on behavioral therapies that could have a significant impact on reducing or eliminating HIV risk behaviors. The main

objective of this initiative is to encourage research that incorporates HIV risk reduction interventions as an integral component in behavioral interventions being tested or research that develops specific modules of HIV risk reduction strategies that can be integrated into existing drug abuse counseling or other treatment interventions. Research supported in both of these areas of nonpharmacological therapies received approximately $35.4 million in FY 1994 AIDS dollars through RPGs, Centers, cooperative agreements, and contracts.

The extent to which projects within the medications development program and the behavioral therapies program should be supported by AIDS funds depends upon one's judgment of whether developing pharmacological and nonpharmacological therapies for drug (specifically opiate) dependency will indeed lead to a reduction of HIV/AIDS-associated risk behavior. This is an especially relevant question, because the HIV risk for those who are dependent on noninjected drugs is mediated through sexual behavior. In this regard, NIDA-supported research suggests that behavioral interventions for drug abuse treatment, such as contingency management, have been effective both in reducing the use of drugs such as cocaine and in reducing AIDS risk behaviors. The use of take-home medications to reinforce drug abstinence also has been effective in retaining patients and reducing cocaine use and AIDS risk behaviors, but this connection is more indirect. Nevertheless, although the Panel generally agreed that drug abuse treatment is a necessary component of HIV prevention, it did not reach consensus about whether all drug abuse treatment research should therefore qualify for AIDS funds.

NIDA Intramural Drug Treatment Research Program

NIDA's intramural AIDS program is contained within its intramural drug treatment research program, housed at the Addiction Research Center in Baltimore, Maryland. Intramural research characterized as behavioral research includes investigations of pharmacological and nonpharmacological treatments for drug addiction. In FY 1994, the NIDA Intramural Research Program (IRP) budget was $24.2 million, of which $5.5 million (23 percent) was supported with AIDS funds. Of that $5.5 million, $3.5 million (63 percent) was devoted to behavioral research.

The AIDS relevance of specific research projects is most questionable within the intramural program. Virtually none of the projects for which the Panel obtained summaries even mentions the words HIV or AIDS. Rather, these studies are focused on testing the effectiveness of various treatment modalities on drug addiction and related behaviors (e.g., hospital visits), irrespective of HIV/AIDS.

The Panel notes that NIDA is currently undertaking significant efforts to tighten the criteria for use of AIDS funds to support drug treatment research in both its extramural and intramural programs. While there were historic reasons for having placed the bulk of the drug treatment initiatives under the AIDS funding umbrella, NIDA has recognized that this may no longer be the most appropriate strategy and is currently reassigning projects and programs to ensure that only those with a clear AIDS focus and connection will be supported in the future by AIDS research dollars. As of FY 1995, new treatment studies must meet all of the following criteria to be considered for AIDS support:

- The study must be designed to determine the efficacy or effectiveness of psychosocial and/or pharmacological treatment interventions for drug dependence that have a high probability of leading to reductions in HIV transmission;

- The target population must be at high risk for HIV infection as a result of either drug injection or sexual behavior associated with their drug use, or be seropositive drug users where the intervention is intended to prevent further spread;

- Both drug use and sexual AIDS risk behaviors must be assessed as part of the research design; and

- HIV risk reduction counseling must be included as part of the research design or intervention under study.

The Panel applauds NIDA's efforts to more clearly define AIDS research in this area.

Out-of-Treatment Drug Users

Since 1987, NIDA has been supporting a program of multisite intervention research targeted at changing the drug-using and sexual behavior of out-of-treatment IDUs, crack cocaine users, and their sex partners. The first iteration of the program was the National AIDS Demonstration Research Projects (NADR), funded from FY 1987 to FY 1992. These projects began with observational research, including ethnographic studies, to characterize the relevant populations and their risk behaviors. This program evolved into a set of interventions employing various models for attempting to change the individual risk behaviors of drug users and their sex partners. As demonstration projects, funded through the R18 mechanism, NADR sites included both intervention research and the provision of services to drug users (e.g., referral to drug treatment, HIV prevention information).

Beginning in FY 1990, the program further evolved to a standardized multisite intervention trial that was then called the Cooperative Agreement for AIDS Community-Based Outreach/Intervention Research. Currently, the program continues to test a variety of models of behavior change, using common protocols, including a standard intervention, and targeted sampling procedures at all sites. Sites test urine for drug use to validate self-report data, and all study participants are offered voluntary HIV testing.

Research currently is under way in 23 sites that are geographically, epidemiologically, and demographically distinct (21 sites in the United States, 1 in Puerto Rico, and 1 in Brazil). Additionally, there is a Data Coordination Center at NOVA Research in Virginia. The program is funded through the cooperative agreement mechanism (U10) and received approximately $23.6 million in FY 1994 funds.

Much has been learned from the community-based outreach program in its different iterations, especially with respect to the possibilities for changing high-risk drug-using behavior among out-of-treatment drug users. Projects have noted significant reductions in such behaviors as needle sharing and the number of drug injection episodes. However, the program also has

demonstrated how difficult it is to change sexual behavior in this population, with most sites reporting less than significant reductions in risky sex among study participants.

Much of the work accomplished with out-of-treatment drug users indicates that certain aspects of an intervention, such as the role and function of the outreach workers, may be critical in achieving successful results. Little is known about the factors contributing to outreach effectiveness because this may not have been the focus of the standard versus enhanced evaluation designs commonly used in NIDA intervention studies. Research to identify which elements of interventions may be related to successful behavior change should be encouraged.

Data from the study have been analyzed on a national level as well as a site-specific level. Current national analysis involves the use of cluster analysis to draw behavioral profiles of the individuals participating in the study and to reduce the heterogeneity of the combined study sample. Results from this analysis are not complete, but the approach offers the ability to draw clearer pictures of the particular sex and drug use behaviors that pose the greatest risk for HIV transmission among different people, and to offer points for more targeted interventions. The community-based outreach program, in its present form as a cooperative agreement, is due to be phased out by 1999, but NIDA anticipates that a number of investigator-initiated projects will be undertaken at these sites in the future.

NIDA Needle Exchange and Needle Hygiene Research

Since FY 1992, NIDA has supported research to reduce the transmission of HIV related to the use of contaminated needles by disinfecting drug-injection equipment (i.e., with bleach) or by increasing the use of new, sterile syringes and needles for drug injection. The provision and exchange of needles/syringes through needle-exchange programs (NEPs) is one strategy. However, legislative restrictions on the use of Federal funds to support NEPs has confined NIDA's involvement to research on already-existing NEPs (as opposed to initiating or supporting the programs themselves). As a consequence, research findings to date on the efficacy of NEPs are confined to explorations at sites throughout the United States and abroad that in many cases have operated illegally or underground.

Notwithstanding these limitations, research supported by NIDA indicates that needle/syringe exchange does appear to reduce the frequency of injecting with contaminated equipment, which should reduce rates of infection. In fact, NIDA-supported research has provided models for estimating the number of new HIV infections averted by a one-for-one syringe exchange.

NIDA's support for NEP research increased from $367,000 in FY 1992 to $2.2 million in FY 1993. NIDA allocated approximately $2.4 million to this effort in FY 1994 and currently supports eight grants in the area. These latter grants are evaluating various models of NEP and the range of drug-using and sharing behaviors in which NEP participants engage.

Needle-exchange studies have been undertaken in a highly charged political arena. Perhaps because of this, NIDA has not been fully able to examine critical issues that it is uniquely situated to investigate. Nevertheless, based on the available data, many studies, reports, and commissions have concluded that needle-exchange efforts reduce HIV risks and do not

contribute to increased injection drug use (National Research Council/Institute of Medicine 1995).

Therefore, the Panel believes that NIDA should now be moving to encourage the development of research away from the question, Are needle exchanges effective in reducing HIV risks? to second-generation questions, such as the following: What is the long-term impact for individuals and communities of participating in needle-exchange programs? Which individuals and communities do not participate in needle-exchange programs and why? What characteristics of needle exchanges affect behavior change? How can drug-user-friendly interventions, such as needle exchanges, be used to reduce sexual risk behaviors and effect positive outcomes, such as reduction in drug use and engagement in educational programs?

Recommendation

53. NIDA should support a "second generation" of studies related to the operations and the impact of needle/syringe-exchange programs on individual participants and communities. The relationship between such programs and other HIV prevention services (including drug treatment) should be particularly encouraged.

B. National Institute of Mental Health (NIMH)

Recognizing the significant role of sexual behavior in the transmission of HIV, NIMH began funding AIDS-related behavior change research in FY 1983. Over the past decade, the portfolio has developed to include not only basic and intervention research but also efforts to improve research methodologies, training, and information dissemination. The Institute's AIDS budget in FY 1994 was $82.7 million, making NIMH the fourth-largest supporter of AIDS research among all NIH ICDs. Of the total, $26.5 million (or 32 percent) is devoted to behavioral and social science research, making NIMH the second-largest supporter of AIDS-related behavioral research at NIH.

NIMH has provided leadership in reducing sexual transmission of HIV. Research funded by NIMH has produced evidence of the efficacy of behavioral and social interventions for reducing transmission of HIV among men who have sex with men (including urban and rural men, older as well as younger men, and men of color), and among adolescents. NIMH has supported general population surveys and basic behavioral and social science research related to HIV risk behaviors. NIMH has used a variety of funding mechanisms (including Centers and Cooperative Agreements) creatively to jump-start the field, even while maintaining a majority of its AIDS funding in investigator-initiated projects.

The NIMH AIDS-related behavioral and social science program supports research in the following major areas (FY 1994 dollars): Primary Prevention Strategies and Interventions ($9.4 million or 35 percent); Secondary and Tertiary Prevention Strategies and Interventions (also referred to as "Consequences of HIV") ($5.7 million or 21 percent); and Basic Behavioral and Social Science Research ($11.1 million or 41 percent). Within these areas are a number of specific programs.

Recommendation

54. NIMH should allocate its AIDS resources in Behavioral and Social Science Research in better accord with the priorities of the NIH Plan for HIV-Related Research, giving a greater proportion to Primary Prevention/Intervention Research.

NIMH Primary Prevention/Intervention Research

The purpose of this program area is to develop effective universal, selective, and indicated primary prevention/interventions to reduce the number of new cases of HIV infection, in particular, through behavior change. Within this domain, NIMH has supported research ranging from national and local sample surveys to face-to-face intensive interventions across a range of populations and social groups. Theory-based interventions that aim primarily at reducing high-risk sexual behavior and maintaining protective behavior are being tested in a range of populations for their efficacy and, recently, their cost-effectiveness. In addition, NIMH has supported some intervention research at the institutional and community levels.

NIMH Multisite HIV Prevention Trial

This program is a seven-site study testing the efficacy of a social-cognitive theory-based behavioral intervention on reducing HIV-related risk behavior in different population groups. It is intended to develop a single intervention that can be tailored for use with different populations in community-based organizations and State and local public health agencies.

The seven research sites are located at Columbia University; University of California, Los Angeles; Medical College of Wisconsin; University of California, Irvine; Emory University; Rutgers University; and Johns Hopkins University. Site-based populations include women in a primary care center and men and women in STD clinics. All seven sites employ a seven-session intervention (Project Light), which is tailored to each group. In addition to behavior change outcomes, sites are collecting biological outcome data related to non-HIV STDs. In addition to the seven sites, there is a Data Coordination Center, located at the Research Triangle Institute in Raleigh-Durham, North Carolina.

Although initiated in FY 1990, the multisite trial program had some difficulty getting underway until FY 1992. Moreover, Phase II pilot intervention studies revealed a number of difficulties with attempting a behavioral trial on such a scale and with such vulnerable populations. Resolution of many of these difficulties resulted in a smaller set of study populations and the use of the standard protocol in Phase III data collection. Data are still being collected from all sites, and published results are not expected until 1997.

The site-based projects are funded under the cooperative agreement mechanism (U10) and each, on average, received about $751,000 in FY 1994. Three of these sites received supplements to their main grants in FY 1994. The Data Coordination Center received $1.6 million in FY 1994 (this includes two supplements). Thus, the multisite program received in total approximately $6,885,346 in FY 1994.

In addition to the multisite program, the NIMH primary prevention portfolio reflects a considerable number of small-group, face-to-face behavior change intervention studies. Many of these intensive workshop or multiple-group interventions have yielded positive evidence of behavior change efficacy and have contributed greatly to advances in scientific knowledge concerning HIV risk behavior change. However, other levels of intervention are less well represented in the portfolio and deserve further attention. On the one hand, research is needed to identify effective one-on-one behavior change interventions, particularly because of the large number of public health venues, such as HIV testing sites and STD clinics, where individual risk reduction counseling is (and will remain) the predominant mode of contact with individuals at high risk for HIV transmission. On the other hand, an increased focus on behavior change interventions at levels greater than the individual or small group is needed. Intervention trials undertaken at the levels of individuals, institutions, and HIV-vulnerable communities may now represent a focus of greater urgency than intensive, small-group interventions whose efficacy has been quite well established with many populations.

Most of the HIV prevention/interventions in the NIMH portfolio are based on cognitive-behavioral or social-cognitive theoretical perspectives. These theoretical frameworks have proven useful and have been the conceptual underpinning of successful small-group interventions. However, as described in a recent Institute of Medicine workshop summary (IOM 1995), other theoretical perspectives may also have relevance to HIV primary prevention behavior change, and efforts should be made to encourage diversity of innovative theoretical perspectives in such prevention research interventions.

Recommendations

55. NIMH should support preventive interventions with a broader range of theoretical perspectives from the behavioral and social sciences than currently is present.

56. NIMH should expand its strong focus on primary prevention trials to support more community- and social (including legal and policy)-level interventions (rather than small-group risk reduction interventions) and to increase emphasis on the maintenance of behavior change.

57. NIMH should encourage multilevel sustained behavior change intervention models that draw upon many different theories and intervention modalities rather than emphasize "pure tests" of single theories. The review process must be sensitive to and reflect recognition of the merits and validity of this approach.

58. NIMH should broaden its support of social science research, including studies of social, policy, and legal change related to HIV prevention and cost-effectiveness and cost-benefit analyses of various HIV intervention modalities.

NIMH has made good use of a variety of support mechanisms including its multidisciplinary Centers, the use of a cooperative agreement mechanism to support the multisite, multi-population clinical trial of HIV prevention interventions, and consortia. These strategies have been innovative, have facilitated scientific advances in HIV prevention/intervention research,

and should be continued and expanded because they draw HIV prevention researchers into collaborative, multidisciplinary investigation.

C. National Institute of Allergy and Infectious Diseases (NIAID)

Although behavioral and social science research is not a priority at NIAID, the Institute has supported a number of projects and components of programs in these areas. In FY 1994, NIAID devoted $8.2 million to AIDS-related BSSR out its total AIDS budget of $511.4 million. Most of this ($5.4 million) was attributed to intervention research supported within the context of the vaccine efficacy trials and the STD centers described below.

NIAID HIV Vaccine Efficacy Trials Network (HIVNET)

HIVNET was established in 1993 as a multisite Phase III trial to test the efficacy of promising vaccine candidates among a range of populations at both domestic and international sites. In the absence of testable vaccine candidates, the current agenda for the program involves continuing baseline studies and implementing nonvaccine studies. These include studies to determine the incidence of HIV in at-risk populations (e.g., IDUs and STD clinic clients) who are likely to participate in future vaccine trials, studies to characterize prevalent viral strains, and feasibility and behavioral studies. The HIVNET program has enrolled 4,800 seronegative persons in eight domestic sites and 17,000 seronegative persons at nine international sites.

The program is supported through five contracts (using the N01 mechanism): a domestic master contract, an international master contract (IMC), a statistical and data coordinating center contract, a laboratory testing contract, and a specimen repository contract. Domestic sites, funded through subcontracts, are in Denver, Boston/Providence, Chicago, New York (two sites), San Francisco, Philadelphia, and Seattle. International sites, also funded through subcontracts, are in Thailand, India, Brazil, Malawi, Kenya, Uganda, Senegal, Haiti, and Zimbabwe.

The subcontracts site awards were funded in FY 1995; hence, the sites do not have complete data yet. The program has nonetheless produced some findings related to the possibilities of recruiting and retaining different at-risk groups and to documenting seroincidence rates.

In FY 1994, only the IMC was categorized by NIAID as having a behavioral component. Of the total $8.5 million in the IMC, approximately $1.7 million supported behavioral research, in particular a study at the Zimbabwe site examining the effect of peer counseling on high-risk behavior.

Currently, NIAID is attempting to integrate behavioral interventions into the HIVNET structure. A preliminary round of proposals was reviewed during the Panel's activities, but only one behavioral intervention received a sufficient rating to be approved for support. That intervention tests the efficacy of computer-assisted survey techniques for obtaining valid and reliable data from interviews, but it does not involve an actual HIV preventive intervention.

The Panel reviewed materials about HIVNET supplied by NIAID, met with NIAID program staff, and consulted researchers familiar with HIVNET's structure. The Panel is concerned that efforts to integrate behavioral interventions within the existing HIVNET program are hampered by two factors: an apparent lack of appropriate expertise in AIDS intervention research within the governing bodies and the shortcomings of the master contract mechanism, which limits the access of potential subcontractors who could provide such expertise.

Recommendation

59. NIAID should not use HIVNET to conduct social and behavioral intervention research unless or until the appropriate expertise can be integrated into the HIVNET governance and review processes.

(See additional discussions of HIVNET in the Vaccine Research and Development and the Natural History, Epidemiology, and Prevention Research Area Review Panel reports.)

NIAID Sexually Transmitted Disease Program

The mission of NIAID's STD program is to develop therapeutics, vaccines, and other preventive methods to prevent and control STDs and their consequences as well as to protect reproductive health. HIV is included as a relevant STD in a number of this program's initiatives. The central theme of this program is the synergism of a combined biomedical, behavioral, clinical, and epidemiological research effort. To this end, a number of projects supported by NIAID, primarily through its STD Centers Cooperative Agreement program (U01), include a behavioral component. In these projects, as well as the handful of investigator-initiated behavioral research projects, HIV infection is not the explicit focus, but is taken to be a relevant STD in some. NIAID estimates that approximately $2.5 million was provided for AIDS-related behavioral research on STDs in FY 1995.

Although the NIAID portfolio includes a number of research projects and centers coded as AIDS-related behavioral and prevention research, the materials provided by the Institute and available for review did not reveal many that can be construed as HIV primary prevention behavioral intervention research. It appears that most of the studies coded as “prevention of high-risk behavior” actually are descriptive studies of the prevalence and determinants of high-risk behavior in populations with, or vulnerable to, STDs or HIV infection. Intervention trials focused on strategies for changing sexual or drug-use risk behavior, whether at the level of individuals, groups, or communities, were not evident in the portfolio. A number of programs funded by different mechanisms appear to support behavioral components, but these are by no means the focus of such programs.

D. National Institute of Child Health and Human Development (NICHD)

NICHD is one of the NIH Institutes that does not focus on a categorical disease but rather on human development from before conception through adulthood. The AIDS research portfolio of NICHD has three main focuses: Reproductive Health; Maternal, Child, and Adolescent Health; and Behavior.

NICHD supports five program areas in AIDS research, all of which include behavioral and social science projects: Demography of Sexual Behavior; the Social Contexts of Sexual Behaviors; Linking Protection from STD/HIV with Protection from Pregnancy; Theory-Based Behavioral Interventions to Prevent the Spread of HIV in Children, Adolescents, and Adults; and Children's Beliefs, Attitudes, and Knowledge about AIDS. Most of the research supported in these program areas is basic science, but a few projects are intervention studies. NICHD primarily employs a mix of RFA and R01 mechanisms to fund most of the relevant research, but it also has used the contract mechanism for some large-scale sample surveys.

Demography of Sexual Behaviors

Underlying this program area is the assumption that understanding the basic demography of human sexual behavior is critical to modeling the spread of HIV/AIDS and crucial to designing and targeting effective sexual behavior interventions. In addition to studying how sexual behaviors are distributed throughout the population, researchers must improve methodologies for measuring these behaviors.

In the middle-1980s, NICHD issued RFPs to design and conduct sample surveys of adult and adolescent sexual behaviors. Although the surveys were designed, they were not conducted as originally intended. Political debates at the time prevented the Federal funding of those specific studies. The adult study was eventually completed on a more modest scale than intended with funding from private foundations.

The FY 1994 budget of $1.4 million in this program area was devoted primarily to smaller sexual behavior surveys that were able to be funded in different populations and to improving computer-assisted interviewing methodologies.

The Social Contexts of Sexual Behaviors

The premise of this program area is that understanding the basic dynamics of human sexual behavior and its various determinants is critical to modeling the spread of HIV/AIDS and to designing and targeting effective behavioral change interventions. Moreover, it is important to recognize the dyadic nature of sexual behavior and to understand the role of social context in which sexual behavior takes place.

In addition to supporting research on sociosexual networks—both domestic and international—this program includes the large-scale longitudinal study of adolescent health (Add-HEALTH), which includes a component on sexual behavior and AIDS risk. The FY 1994 budget for this program area was $3.7 million, much of it dedicated to the Add-HEALTH study.

Linking Protection From STD/HIV With Protection From Pregnancy

This program area investigates the links between decisions about pregnancy prevention and STD/HIV prevention. A growing awareness exists that many women who choose certain effective pregnancy prevention methods such as hormonal contraceptives or sterilization are not protected against STD transmission, including HIV infection.

This program area supports projects investigating attitudes and behavior related to condom use for pregnancy prevention versus STD/HIV prevention among women and men. The FY 1994 budget of $25,000 reflects only those portions of projects in this area of research that are not covered under other program areas.

Theory-Based Behavioral Interventions To Prevent the Spread of HIV in Children, Adolescents, and Adults

This program area supports research to improve the basic understanding of how to provide individuals of all ages with skills to resist risky behaviors that expose them to HIV infection. NICHD has been supporting successful theory-based interventions in risk behavior for nearly two decades (predating AIDS). Current AIDS-related projects evaluate interventions and the theoretical models upon which they are based in racial/ethnic minority communities and populations of middle-school youth.

Most of the intervention studies supported by NICHD have evaluated small-group, face-to-face, behavior change interventions of short duration undertaken in schools, health facilities, or community settings. A few studies focus on early adolescence and a few on late adolescence. Various models have been tested, including a counseling model, health belief model, and self-help model. However, there has been no effort to evaluate these interventions in large-scale community trials. The Panel believes that if NICHD is committed to evaluating behavior change interventions, it should expand its primary prevention/intervention research portfolio, in both number and scope of projects, to include youth of all ages and interventions in and out of school settings.

Children's Beliefs, Attitudes, and Knowledge About AIDS

The purpose of this program area is to improve the basic understanding of children's beliefs, attitudes, and knowledge about AIDS in order to facilitate the development of AIDS-related educational materials for use in the Nation's schools and other institutions. Research supported by this program addresses children's perceptions of vulnerability and their understanding of AIDS as a disease. This area received $183,000 in FY 1994.

Although it is increasingly evident that adolescents are a particularly vulnerable population for HIV transmission, there appears to be little connection between the education-based projects of NICHD and the Division of Adolescent School Health program of the CDC.

The Panel found that, overall, NICHD has funded few studies of vulnerable populations, such as homosexual youth, and has funded very few interventions with children and youth.
In addition, NICHD has no mechanisms in place to allow the transfer of information to community and service organizations. The Panel would like to see NICHD move quickly to redress these gaps in its AIDS research program.

Recommendation

60. NICHD should support more HIV preventive intervention research focused on youth most vulnerable to HIV infection and should develop mechanisms for disseminating findings from such research to communities and service organizations.

E. National Institute on Alcohol Abuse and Alcoholism (NIAAA)

The entire budget for AIDS research at NIAAA in FY 1994 was approximately $9.5 million (about 5 percent of total NIAAA funding and less than 1 percent of total NIH AIDS funding). Of that amount, NIAAA invested only about $391,000 for primary prevention/intervention research and $3.4 million for pre-intervention research (some of which is coded as Epidemiology). NIAAA's total budget for behavioral and social science research in FY 1994 was $2.8 million.

Although NIAAA's AIDS budget is small when compared with most other ICDs, its AIDS-related studies produce high yields and, therefore, should be aggressively encouraged and promoted. NIAAA supports a relatively good amount of descriptive (basic) behavioral research regarding the relationship between alcohol use and risk of HIV transmission, but the portfolio does not reflect sufficient research on HIV prevention/interventions in alcohol-related contexts or alcohol-using populations. Specific areas of research that could be better represented include preventive intervention outcome studies that examine the relationship between alcohol, drug use, and HIV risk, particularly for drug injectors and crack smokers.

NIAAA also should utilize AIDS funds only for research that can be expected to have direct relevance to AIDS. The Panel questions whether some of the projects coded as AIDS-related really have relevance to the epidemic. For example, NIAAA's FY 1994 portfolio lists research that tests contrasting theoretical predictions about the impact of varying levels of alcohol use on a reaction time task. Although this research may expand knowledge of the processes that underpin cognitively based theories of social behavior, its relationship to HIV prevention is debatable.

Recommendations

61. NIAAA should be commended for its effort to support HIV-related behavioral research with such a small budget. However, a better balance should be struck between pre-intervention and primary prevention/intervention research, requiring that greater resources be devoted to the latter over the next few years.

62. NIAAA and other Institutes such as NIDA or NIMH should develop methods to foster greater integration and collaboration on intervention (as well as basic science) research on the relationship between alcohol, other drug use, and HIV transmission risk. These could include (1) joint development and support of RFAs; (2) representatives from other NIH Institutes (such as NIDA or NIMH) participating in

program reviews for NIAAA; (3) specific RFPs, jointly sponsored, to encourage intervention research related to alcohol and drug use and HIV transmission risk behaviors and their contexts (particularly with respect to drug injectors and crack cocaine users).

F. National Institute for Nursing Research (NINR)

NINR has supported HIV/AIDS research since 1988, and its program has grown from $600,000 in that year to about $4 million in FY 1995. NINR's program emphasizes four priority areas: physiological aspects of nursing care of patients with HIV (symptom management), psychosocial aspects of care, delivery of care, and prevention of HIV transmission.

In FY 1994, NINR supported behavioral and social science research in four program areas: Youth Risk ($774,565); Minority Women Risk ($783,736); Response to Illness ($148,649); and Quality of Care ($601,556), for a total of $2.3 million. Some of this research has been collaborative with other ICDs. For example, NINR has collaborated with NICHD in research aimed at increasing healthy behaviors of children and reducing risky behaviors in adolescents.

Within NINR's small research portfolio, other AIDS education and intervention projects are aimed at reducing the risk behavior of adolescents and minority women and assessing the quality of care provided by nurses to people with HIV/AIDS. The Panel did not have any specific recommendations to make about the NINR program.

G. National Institute on Aging (NIA)

NIA supports a modest number of HIV/AIDS behavioral research studies—only six projects for a total of $670,000 in FY 1994. All six projects were coded by NIA as intervention research, although most are in fact descriptive studies. All are R01s, and three actually have other ICDs as their primary sponsor.

In 1987, as part of a general effort to develop a funding program on AIDS, the Behavioral and Social Research Program of NIA commissioned a set of state-of-the-art papers on HIV from experts with varied backgrounds. The goal was to identify a set of research issues and to pull together scientific knowledge about selected topics pertaining to the social and behavioral aspects of AIDS in middle and later years. This work culminated in a 1989 workshop attended by the authors, NIA program staff, and representatives from other ICDs. Many of the papers subsequently were published in *AIDS in Aging Society: What We Need to Know* (Matilda White Rile, Marcia G. Ory, and Diane Zablotsky [eds.], New York: Springer, 1989).

NIA has not yet issued its own program announcement or RFA specifically targeted to AIDS and aging issues, but it has cosponsored PAs from other ICDs. Currently, NIA is collaborating with NIMH on two AIDS-related solicitations: the FY 1995 RFA on "Family Interventions and HIV/AIDS" and a new NIMH PA on "Brief Interventions to Prevent the Spread of HIV." In addition, NIA cosponsored the National AIDS Behavioral Research Survey (NABS) with NIMH, which is the only national survey of sexual behaviors, HIV test-seeking, HIV-related beliefs, and IDU that includes older persons. In FY 1995, NIA cofunded the new Family of

AIDS Behavioral Surveys to provide support for primary data collection on older persons (50 years and older) regarding AIDS risks and caregiving issues. This survey will permit a longitudinal examination of changes in prevalence of HIV risk factors, HIV/AIDS-related beliefs, and sexual negotiation skills over time. Other than cosponsoring these surveys, NIA's major commitment in AIDS behavioral research is a grant supporting a project on stress and coping among AIDS caregivers.

Based on the information and project abstracts available for this review, it appears that NIA supports only one study that might be construed as HIV primary prevention/intervention. This is a U.S. Agency for International Development-sponsored project testing the effectiveness of peer education on HIV prevention among women. NIA awarded supplemental funds for limited pilot work to test the effectiveness of different models for implementing peer-based interventions among middle-aged and older women.

Although the significance of HIV risk among some mid-life and older women is now recognized, the NIA portfolio reflects little or no support for HIV primary prevention behavior change interventions with older Americans at risk. This is a clear limitation in the field.

The Panel was distressed to learn that NIA did not propose an AIDS budget to the OAR for FY 1997. This gives the appearance that NIA is no longer committed to AIDS research. Given NIA's longstanding history and commitment to social and behavioral research at the NIH, and given the increased longevity of people with AIDS who will be dealing with a chronic disease into late adulthood, the Panel believes it is appropriate and necessary for NIA to become a more active participant in AIDS research.

Recommendation

63. The Panel recommends that NIA resume its commitment to HIV/AIDS and aging research by issuing its own PA, RFA, or RFP, in addition to participating in those initiated by other ICDs.

References

Institute of Medicine. 1994. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie [eds.]. Washington, DC: National Academy Press.

Institute of Medicine. 1995. *Assessing the Social and Behavioral Science Base for HIV/AIDS Prevention and Intervention: Workshop Summary*. Washington, DC: National Academy Press.

National Commission on AIDS. 1993. *Behavioral and Social Sciences and the HIV/AIDS Epidemic*. Washington, DC: National Commission on AIDS.

National Research Council and Institute of Medicine. 1995. *Preventing HIV Transmission: The Role of Sterile Needles and Bleach*. Jacques Normand, David Vlahov, and Lincoln E. Moses [eds.]. Washington, DC: National Academy Press.

Oakley, A., D. Fullerton, J. Holland, et al. 1995. Sexual health education interventions for young people: A methodological review. *British Medical Journal* 310:158-162.

Public Media Center. 1995. *The Impact of Homophobia and Other Social Biases on AIDS*. San Francisco, CA: Public Media Center.

Appendix A

Defining AIDS and AIDS-Related Research: A Modest Proposal

The Behavioral, Social Science, and Prevention Research Area Review Panel initiated discussion to consider ways to better define AIDS research for scientific and budgetary purposes. Below is presented the Panel's collective thinking on a possible schema for determining the AIDS-relatedness of projects in the behavioral and social sciences (with some biomedical analogies suggested). The Panel does not see this as a final proposal, but rather as an initial foray into the discussion.

A graded system with five categories rather than a simple dichotomy is proposed because it allows more flexibility and demonstrates a recognition that defining AIDS-relatedness is a complex issue. In this schema, research in the first three categories may be considered AIDS-related and would be appropriate for funding with AIDS-designated funds, although those in the third require more clear justification than those in the first two. Research in the fourth category should rarely receive AIDS funding, and research in the fifth should not be considered appropriate for AIDS funding.

Grading System

I. ***AIDS-Targeted, Direct Studies of HIV/AIDS***

A. Address questions of immediate importance to HIV/AIDS

B. Study directly HIV-infected or at-risk subjects, HIV/AIDS epidemiology, biology of the virus, and the like.

Examples in Behavioral Research:

1. Studies of prevention of HIV infection in high-risk populations where the incidence of HIV infection is a principal outcome variable.

    a. Needle-exchange programs with this outcome would fall under this category.

2. Psychological and social consequences of HIV infection in those infected, their close relationships, caregivers, and communities.

Biomedical Analogs[1]

1. Studies of the molecular biology of HIV-1.

---

[1]The biomedical analogs are provided both with a view to developing a common rating system across disciplines and to clarifying the point of view of this rating.

2. Studies of the pathogenesis of HIV infection, immune changes, brain dysfunction.

3. Treatment/prophylaxis of HIV and its complications.

(This is the easiest group to deal with. It includes studies that everyone would accept as directly AIDS-related.)

II. ***AIDS-Targeted, Indirect Studies Related to HIV/AIDS***

A. Address questions of immediate importance to HIV/AIDS. They are driven by HIV/AIDS issues and have a close applicability to these issues. HIV/AIDS is thus the central rationale for the overall study and its individual components.

B. Do not directly study either HIV-infected/high-risk subjects or the epidemiology/biology of the virus.

Examples in Behavioral Research

1. Studies of prevention of HIV risk behaviors in vulnerable populations in which the change in risk behavior is the primary outcome measure.

2. Studies of the epidemiology/demographics of HIV risk behaviors in vulnerable populations and subpopulations.

3. Basic research on the determinants of HIV risk behaviors in vulnerable populations and subpopulations.

4. Methodological studies related to performing the above targeted studies.

Biomedical Analogs

1. Studies of the molecular, cellular biology of related lentiviruses.

2. Pathogenetic studies of lentivirus and other related retroviral animal models.

(This category includes basic research that provides fundamental knowledge related to HIV/AIDS or that will guide additional research more directly related to HIV/AIDS.)

III. ***AIDS-Applicable Studies Not Immediately Targeted to HIV/AIDS***

A. Address questions of interest to HIV/AIDS, but less directly than categories 1 and 2 above. Provide important background information and foundation knowledge for HIV/AIDS.

B. Do not directly study either HIV-infected/high-risk subjects or the biology/epidemiology of the virus.

Examples in Behavioral Research:

1. A general survey of sexual practices in the population at large.

2. Studies of behavior/epidemiology in which other STDs are the focus and outcome variable and serve as a surrogate for HIV transmission.

Biomedical Analogs

1. Studies of T-cell receptor function.

2. Studies of cellular transcription factors shared by or influencing HIV replication.

(These studies deal with biological/medical/psychosocial issues that may be narrow or broad, not conceived or executed solely to address primarily questions of HIV/AIDS but provide background information that may be fundamental or even essential to the AIDS research effort. They therefore should be eligible for AIDS funding, but the justification for this should be clearly and individually articulated.)

IV. ***AIDS-Applicable Studies Not Targeted to HIV/AIDS***

A. Address research issues that may be of interest to HIV/AIDS, but not driven solely by HIV/AIDS issues or questions. Do not provide background information currently considered important or essential to the AIDS research effort.

B. Do not directly study either HIV-infected/high-risk subjects or the biology/ epidemiology of the virus.

Examples in Behavioral Research

1. Programs dealing with the general issues of injection drug use and addiction, including its treatment (e.g., methadone) or neurobiology.

Biomedical Analogs

1. Studies of the hypothalamic-pituitary-adrenal axis and other issues in psychoneuroimmunology.

(These studies deal with biological/medical/psychosocial issues that are not conceived or executed primarily to address questions of HIV/AIDS. They may have some general applicability to HIV/AIDS, but this is not

judged to be important or essential to the AIDS research effort. Therefore, they generally should be ineligible for AIDS funding.)

V. ***Studies Unrelated to HIV/AIDS***

A. Address questions with only remote application to HIV/AIDS. They are not driven by HIV/AIDS issues.

B. Do not directly study either the biology of the virus or HIV-infected/at-risk subjects.

Examples in Behavioral Research

1. Studies of behavioral avoidance techniques related to other diseases, e.g., smoking.

2. Studies of bereavement in cancer or other terminally ill patients.

Biomedical Analogs

1. Studies of neuropathogenesis of viruses other than lentiviruses.

2. Studies of neuronal excitotoxicity.

3. Studies of the hypothalamic-pituitary-adrenal axis and other issues in psychoneuroimmunology.

(These studies deal with biological/medical/psychosocial issues that may be of general interest, but they are not conceived or executed to address questions of HIV/AIDS. Nor do they stand out as directly linked to HIV/AIDS. Their exclusion from funding is based on the fact that there is a limit to AIDS-related funding and that other sources of funding exist for these type of studies.)

Implementation

Ensuring the Scoring System

There may be at least three levels of declaration and check on the 'grading' of AIDS-relatedness using the above scale:

1. The grantee/principal investigator (PI). AIDS applications should have a check box and a space for justifying the categorization by the PI (in 25 words or less).

2. The review section. Part of the review should include judging the validity of the investigator's declaration and modification if needed.

3. Independent review panel. Either completely or on a sampling basis, a panel should be asked to judge the validity of the investigator's and the review panel's categorization and modify them as appropriate.

Use in Funding Allocation

Categories I and II should be eligible for AIDS funding without qualification (assuming successful peer review). Category III requires justification, but if relevance is clear would also be eligible for AIDS funding. Category IV should rarely receive AIDS dollars, and Category V would not be eligible for AIDS funding. An ICD's portfolio should not contain a disproportionate number of Category IIIs.

Appendix B

Roster of Panel Members

Thomas J. Coates, Ph.D.
Chair
Professor of Medicine and
Director
Center for AIDS Prevention Studies
University of California, San Francisco

John Bancroft, M.D.
Director
Kinsey Institute
Indiana University

Floyd E. Bloom, M.D.
Chairman
Department of Neuropharmacology and
Director, Center on AIDS Dementia,
Molecular and Cellular Mechanisms
The Scripps Research Institute

Sherry Deren, Ph.D.
Director
Institute for AIDS Research
National Development and Research
Institutes

Rafael M. Diaz, Ph.D.
Associate Professor of Medicine
Center for AIDS Prevention Studies
University of California, San Francisco

Ferd Eggan
AIDS Coordinator
City of Los Angeles

Loretta S. Jemmott, Ph.D., R.N., F.A.A.N.
Associate Professor
School of Nursing
University of Pennsylvania
(Resigned, September 25, 1995)

Jeffrey A. Kelly, Ph.D.
Professor of Psychiatry and
Director
Center for AIDS Intervention Research
Medical College of Wisconsin

Judith A. Levy, Ph.D.
Associate Professor of Health Policy
and Administration
School of Public Health
University of Illinois, Chicago

Michael Merson, M.D.
Dean of Public Health
Chairman
Department of Epidemiology and
Public Health
Yale University School of Medicine

Richard W. Price, M.D.
Chief, Neurology Service
San Francisco General Hospital and
Professor of Neurology
University of California, San Francisco

Mike Shriver
Director of Public Policy
National Association of
People with AIDS

Freya Sonenstein, Ph.D.
Director
Population Studies Center
The Urban Institute

Ezra Susser, M.D., Dr.P.H.
Associate Director
HIV Center for Clinical and Behavioral
Studies
Columbia University and
New York State Psychiatric Institute

Liaison from Natural History, Epidemiology, and Prevention Research Panel:

Margaret Chesney, Ph.D.
Professor of Medicine and
Co-Director
Center for AIDS Prevention Studies
University of California, San Francisco

OAR Staff:

Judith D. Auerbach, Ph.D.
Executive Secretary
Behavioral and Social Science
Coordinating Chair
Office of AIDS Research
National Institutes of Health

Paul Gaist, M.P.H.
Senior Program Analyst
Office of AIDS Research
National Institutes of Health

Diane Jones
Program Assistant
Office of AIDS Research
National Institutes of Health

Appendix C

Biographies of Panel Members

Thomas J. Coates, Ph.D., Panel Chair, is Director and Principal Investigator of the Center for AIDS Prevention Studies, and Professor of Medicine, at The University of California, San Francisco (UCSF). Dr. Coates came to UCSF from Johns Hopkins in 1982. Previously, he was on the faculty of the Stanford Heart Disease Prevention program. His interests and experience focus on the study of disease-related behavior, with an emphasis on interventions to modify behaviors. He is the author of many publications on the effects of antibody testing on high-risk behavior, the efficacy of strategies to modify high-risk behavior, the relationship between psychosocial variables and AIDS-related immune dysfunction, and clinical illness and intervention to reduce high-risk behavior among seropositive men. His current research involves studies to reduce high-risk behaviors in several populations, including African-Americans, Asians, young gay men, teens, and heterosexual adults. He is a special advisor to Family Health International's AIDS Prevention Project, sponsored by the U.S. Agency for International Development (USAID), and he has chaired WHO's Global Programme on AIDS Steering Committee, Social and Behavioral Studies Unit.

John Bancroft, M.D., is Director of the Kinsey Institute for Research in Sex, Gender and Reproduction, and Professor of Psychiatry at Indiana University, where he has been since 1995. He was previously Clinical Consultant at the Medical Research Council's Reproductive Biology Unit in Edinburgh, Scotland. Dr. Bancroft is the author of Human Sexuality and Its Problems (2nd edition, 1989) and was until recently Editor of *Annual Review of Sex Research*. Currently he is President-elect of the International Academy of Sex Research. He has extensive research and clinical experience in the relationship of reproductive hormones to sexuality and well-being, psychophysiology and pharmacology of sexual response, and the management of sexual problems.

Floyd E. Bloom, M.D., is Chairman of the Department of Neuropharmacology and Director of the Center on AIDS Dementia: Molecular and Cellular Mechanisms at The Scripps Research Institute. Previously, he was Director of Behavioral Neurobiology at the Salk Institute and Chief of the Laboratory of Neuropharmacology of the National Institute of Mental Health. A member of the National Academy of Sciences and the Institute of Medicine, Dr. Bloom has received numerous awards, including the Pasarow Award in Neuropsychiatry and the Hermann von Helmholtz Award, as well as a number of honorary degrees from major universities. He attended Southern Methodist University in Dallas, Texas, where he received an A.B. degree cum laude and then an M.D. degree from Washington University in St. Louis, Missouri. He is past President of the Society for Neuroscience, The American College of Neuropsychopharmacology, and the Research Society on Alcoholism. On May 1, 1995, he became Editor-in-Chief of *Science Magazine*.

Sherry Deren, Ph.D., is Director of the Institute for AIDS Research at National Development and Research Institutes, Inc. (NDRI). She has been principal investigator on many projects related to drug abuse and AIDS prevention. She is currently the principal investigator for the

New York site of a NIDA-funded Cooperative Agreement to monitor HIV-related risk behaviors and evaluate an intervention for injection drug users and crack smokers. Before coming to NDRI, Dr. Deren was Chief of Evaluation for the New York State Division of Substance Abuse Services, responsible for the evaluation of a wide range of drug treatment and prevention programs. She is the author of many articles on program evaluation and HIV/AIDS prevention.

Rafael M. Diaz, Ph.D., is Associate Professor of Medicine at the Center for AIDS Prevention Studies (CAPS), University of California, San Francisco (UCSF), which he joined after 13 years as a Professor of Psychology and Education at the University of New Mexico and Stanford University. He received his M.S.W. degree from New York University and his Ph.D. from Yale University. His current research is aimed at identifying sociocultural barriers to safer sex practices in Latino gay/bisexual men and in developing culturally relevant risk-reduction interventions in this community. During the past 3 years, Dr. Diaz has maintained ongoing working collaborative relationships with different local and national community-based organizations (CBOs) that provide HIV education and prevention to gay men of color. He has conducted outcome evaluations of three different community programs and has assisted several CBOs in the design of HIV risk-reduction projects targeting Latino gay/bisexual men with empowerment models of intervention. Recent publications include *Latino gay men in the Southwestern United States*, and *HIV risk in Latino gay/bisexual men: A review of behavioral research*.

Ferd Eggan is AIDS Coordinator for the City of Los Angeles and a person living with HIV disease since he tested positive in 1985. He developed the current behavior modification initiatives in AIDS prevention for Los Angeles and has been an active member of the Los Angeles County Commission on HIV Health Services since its inception, working to plan for the distribution of funds for AIDS services and health care. His AIDS work stems from personal commitment and long-time involvement in civil rights activism, alternative education, and gay/lesbian liberation. Eggan was a founder of the national ACT UP Network and the former Executive Director of Being Alive: People with HIV/AIDS Action Coalition, before joining the ranks of government. He is also a writer with two published books: *Your LIFE Story, by someone else* and *Pornography*.

Loretta Sweet Jemmott, Ph.D., R.N., F.A.A.N., is an Associate Professor of Nursing at the University of Pennsylvania School of Nursing. She received her master's degree in nursing and her Ph.D. in education from the University of Pennsylvania. Over the past 10 years she been involved in a program of research on the elucidation of the modifiable psychological factors that underlie behaviors that create risk for sexually transmitted HIV infection among inner-city African-Americans, particularly women and adolescents. She has authored and edited numerous articles in leading journals, books and book chapters, and textbooks. Recently, Dr. Jemmott's HIV prevention curriculum entitled “Be Proud! Be Responsible! Strategies to Empower Youth to Reduce Their Risk for AIDS” was selected by the CDC, Division of Adolescent and School Health programs, as a model curriculum to be disseminated nationally as part of the “Research to Classroom: Projects that Work!” program. Dr. Jemmott is a member of the Sigma Theta Tau International Nursing Honor Society, a Fellow at the American Academy of Nursing, and a member of the National Institute of Nursing Research Advisory

Council. She has also won several awards for her work, including the 1992 Governor of New Jersey Nurse Merit Award.

Jeffrey A. Kelly, Ph.D., is Professor of Psychiatry and Behavioral Medicine and the Director of the Center for AIDS Intervention Research (CAIR) at the Medical College of Wisconsin. Dr. Kelly received his Ph.D. in clinical psychology from the University of Kentucky. He is the author of approximately 175 scientific research articles, as well as book chapters and books. Dr. Kelly's studies evaluate determinants of risk behavior as well as individual, group, and community-level interventions to change risk behavior in AIDS-vulnerable populations including gay men, disadvantaged women, the chronic mentally ill, and the homeless.

Judith A. Levy, Ph.D., is Associate Professor of Health Policy and Administration in the School of Public Health, University of Illinois-Chicago. Having received her doctorate in medical sociology from Northwestern University, she also completed a postdoctoral fellowship in life course studies with the Midwest Council for Social Research on Aging. She has authored numerous articles and two edited volumes examining the social experiences of health and illness. Current research includes a study of using street-based case management to reduce injecting drug-use and HIV transmission, an evaluation of an AIDS educational program for older adults, and an assessment of the efficacy of using an outreach assistance model to encourage HIV partner notification among active IDUs. She has served as a member of the National Institute on Aging Advisory Group on AIDS and also the WHO Global Programme on AIDS Workgroup for conducting cross-national qualitative HIV research, which was convened in Geneva to develop guidelines and a training manual.

Michael H. Merson, M.D., is Dean of Public Health and Chairman of the Department of Epidemiology and Public Health at Yale University School of Medicine. Dr. Merson assumed this position in April 1995. Prior to that he worked for 17 years with the World Health Organization (WHO), serving first as Director of the WHO Diarrheal Diseases Control and Acute Respiratory Control Programs and subsequently as Executive Director of the WHO Global Programme on AIDS. Before joining WHO, Dr. Merson was engaged in research on the etiology and epidemiology of diarrheal diseases in the United States and abroad and authored over 150 publications on this subject. More recently he has written on global AIDS policy issues, which is his current major area of interest. He has received two commendation medals from the U.S. Public Health Service and is a recipient of the Arthur S. Flemming Award for distinguished government service.

Richard W. Price, M.D., is Chief of the Neurology Service at San Francisco General Hospital and Professor of Neurology, University of California, San Francisco. Previously, he was Professor and Head of the Department of Neurology at the University of Minnesota Medical School in Minneapolis. He received his M.D. from Albany Medical College and completed his neurology residence at Cornell University Medical College. Dr. Price's expertise is in the field of neurological aspects of HIV-1 infection and AIDS, and his major research interests include those related to understanding the AIDS dementia complex, including clinical characterization, pathogenesis, and treatment. He was a member of the IOM Committee on Substance Abuse and Mental Health Issues in AIDS Research and is editor of *The Journal of Neuro-AIDS.*

Michael Shriver is the Director of Public Policy for the National Association of People With AIDS. From 1993 until December 1995 he served as the Executive Director of Mobilization Against AIDS in San Francisco, where he worked on protecting and augmenting Federal funding for HIV/AIDS prevention and care, and on the creation and establishment of the Comprehensive HIV Prevention Working Group under the auspices of the Department of Health and Human Services. Mr. Shriver served on the steering committee convened by the National Institutes of Health to examine ethical aspects of HIV prevention vaccines. He is also the former public policy director of 18th Street Services (San Francisco), the Nation's largest outpatient drug and alcohol counseling program for gay and bisexual men. Mr. Shriver has been a plenary speaker and keynote speaker in various HIV/AIDS conferences throughout the United States.

Freya L. Sonenstein, Ph.D., is director of the Population Studies Center at The Urban Institute in Washington, DC. Before returning to The Urban Institute in 1989, Dr. Sonenstein codirected the program on Families and Children at the Florence Heller School of Advanced Studies, Brandeis University. She is the principal investigator of the National Survey of Adolescent Males, a research project that has provided information about sexual behavior and condom use among American male teenagers since it was first fielded in 1988. Her primary research interests include the development of better measures of sexual behavior, the identification of factors associated with sexual risk behavior among teenagers, and the assessment of the effects of program participation on behavior. Dr. Sonenstein is the author of numerous articles about male sexual behavior, adolescent fertility, and family planning.

Ezra Susser, M.D., Dr.P.H., is Associate Professor of Clinical Psychiatry and Epidemiology at Columbia University. He is also Associate Director of the HIV Center for Clinical and Behavioral Studies and Head of the Division of Epidemiology and Community Psychiatry (Department of Psychobiology) at the New York State Psychiatric Institute. Dr. Susser's areas of expertise include both clinical psychiatry and epidemiology. His work has focused on the prevalence and the causes of homelessness and, more recently, on prevention of HIV infection in homeless populations. In addition, he has contributed work on the etiology and treatment of schizophrenia and, more recently, on the risk factors for and prevention of HIV infection among men and women with schizophrenia.

Margaret A. Chesney, Ph.D., is Professor of Medicine, School of Medicine, University of California, San Francisco. Dr. Chesney received a Ph.D. in counseling-clinical psychology from Colorado State University and completed postdoctoral training in psychiatry at Temple University School of Medicine. She is currently the Co-Director of the Center for AIDS Prevention Studies at the University of California, San Francisco, where she is engaged in research on the relationship between behavior and chronic illness, on behavioral factors in clinical trials, and on the development and evaluation of behavioral treatment of health problems. She has served as President of the Division of Health Psychology of the American Psychological Association and as a Board Member of the Society of Behavioral Medicine, the Academy of Behavioral Medicine Research and the Contributions to the APA Division of Health Psychology in 1982 and 1986, and the President's Award from the Academy of Behavioral Medicine Research in 1987. Dr. Chesney has authored and coauthored over 130 scientific publications and book chapters and is coeditor of two major books on women's health.

Dr. Chesney's areas of expertise include behavioral science, coping with HIV, and women's health.

Judith D. Auerbach, Ph.D. (Executive Secretary), is the Behavioral and Social Science Coordinating Chair in the Office of AIDS Research at the National Institutes of Health. She oversees activities related to the development of scientific and budgetary priorities for AIDS research in the social and behavioral sciences across the NIH. Prior to coming to the NIH, Dr. Auerbach was a Senior Program Officer at the Institute of Medicine/National Academy of Sciences, where she was Study Director for the Committee on Substance Abuse and Mental Health Issues in AIDS Research. She coedited that committee's 1994 report, *AIDS and Behavior: An Integrated Approach* (National Academy Press). Dr. Auerbach received her Ph.D. in sociology from the University of California, Berkeley. She began her policy work in Washington in 1988 as a Congressional Science Fellow, sponsored by the Society for Research in Child Development. She has published and presented in the areas of child and family policy, HIV/AIDS prevention, behavioral and social science policy, and women's health research.

Appendix D

Schedule of Meeting Dates and Major Agenda Items

May 3, 1995 **First Meeting of ARP** (Bethesda, MD)

- ♦ Define domain
  (e.g., include neuroscience; overlap with Epidemiology and Natural History Panel)
- ♦ Determine organization of domain
  (e.g., by program within ICD; by OAR Plan categories; other)
  - ♦ Determine subpanels
  - ♦ Determine criteria for evaluation (e.g., how to measure effectiveness, balance, AIDS focus, appropriate use of money; use of mechanisms; duplication; collaboration; vision)
  - ♦ Determine information needs

May 11 **Conference Call with Natural History and Epidemiology Panel Chair**

June 5-6 **Second Meeting of ARP** (Bethesda, MD)

- ♦ Invited ICD representatives describe their AIDS programs
- ♦ Subpanel reports - preliminary assessments of materials

July 5 **Conference Call: Basic/Observational Subpanel**

July 5 **Conference Call: Consequences Subpanel**

July 11 **Conference Call: Interventions Subpanel**

July 14 **Conference Call: Basic/Observational Subpanel**

July 17 **Third Meeting of ARP (Bethesda, MD)**

- ♦ Subpanels present interim reports to whole Panel
- ♦ Presentation from Dr. Wendy Baldwin on "Reinvention" Issues; Peer Review

Aug. 4 **Conference Call: Interventions Subpanel**

Aug. 28 **Conference Call: Interventions Subpanel**

Aug. 31-Sept. 1 **Fourth Meeting of ARP (Bethesda, MD)**

- ♦ Discuss subpanel reports

Sept. 5 **Conference Call: Neuro-AIDS Subpanel (with Etiology and Pathogenesis Panel)**

Sept. 15 **Conference Call: Interventions Subpanel**

Sept. 26 **Conference Call: Interventions Subpanel**

Sept. 28 **Fifth Meeting of ARP (San Francisco, CA)**

- ♦ Discuss subpanel reports
- ♦ Discuss full Panel report

Oct. 2 **Conference Call: Joint HIVNET Subpanel**

Nov. 2 **Sixth Meeting of ARP (Washington, DC)**

- ♦ Public meeting
- ♦ Discuss Panel report and recommendations

Nov. 28 **Seventh Meeting of ARP (Bethesda, MD)**

- ♦ Discuss Panel report and recommendations

Appendix E

Acknowledgments

The Panel would like to thank the people listed below who, through presentations, conversations, and the submission of written materials, provided information important to our work. Affiliations are those at the time of contact.

MerriBeth Adams
Advanced Peptides & Biotechnology Sciences

John Anderson
American Psychological Association

Christine Bachrach
National Institute of Child Health and Human Development

Wendy Baldwin
Office of the Director
National Institutes of Health

Kendall Bryant
National Institute on Alcohol Abuse and Alcoholism

Cynthia Costello
American Sociological Association

William Darrow
Florida International University

Kathryn De Leon
ACT UP New York and Native American AIDS Caucus

Walter Goldschmidt
National Institute of Mental Health

Karl Goodkin
American Psychiatric Association

E. Michael Gorman
University of Washington

Donald Grove
Lower East Side HARM Reduction Center

Steven Gust
National Institute on Drug Abuse

Harry Haverkos
National Institute on Drug Abuse

Penelope Hitchcock
National Institute of Allergy and Infectious Diseases

Rod Hoff
National Institute of Allergy and Infectious Diseases

Leslie Isaki
National Institute on Alcohol Abuse and Alcoholism

Michael Isbell
Gay Men's Health Crisis, Inc.

Peggy Johnston
National Institute of Allergy and Infectious Diseases

Norman Krasnegor
National Institute of Child Health and Human Development

Alan Leshner
National Institute on Drug Abuse

Felice Levine
American Sociological Association

June Lunney
National Institute of Nursing Research

Leonard Mitnick
National Institute of Mental Health

Richard Needle
National Institute on Drug Abuse

Susan Newcomer
National Institute of Child Health and Human Development

Marcia Ory
National Institute on Aging

Mary Margaret Overbey
American Anthropological Association

Willo Pequegnat
National Institute of Mental Health

Zeda Rosenberg
National Institute of Allergy and Infectious Diseases

Mona Jaffe Rowe
National Institute of Child Health and Human Development

Jeanne Wallace Ruttle
Private Citizen

Jean J. Schensul
Society for Applied Anthropology

Stanley Schneider
American Psychological Society

Angela Sharpe
Consortium of Social Science Associations

Amy Sheon
National Institute of Allergy and Infectious Diseases

Sharilyn Stanley
National Institute of Allergy and Infectious Diseases

Ellen Stover
National Institute of Mental Health

Recky Waiss
Lower East Side HARM Reduction Center

Anne Willoughby
National Institute of Child Health and Human Development